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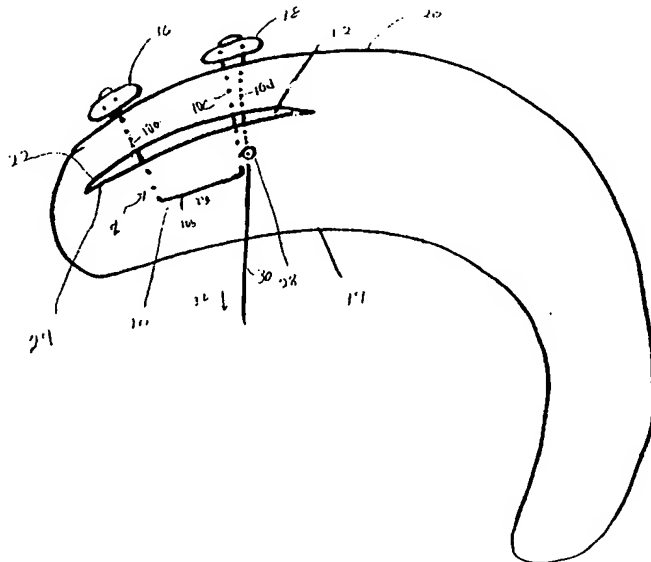
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[Continued on next page]

(54) Title: CLOSURE DEVICE AND METHOD FOR TISSUE REPAIR



(57) Abstract: A surgical method includes positioning a fixation member relative to tissue, moving a flexible member coupled to the fixation member relative to the fixation member to bring two tissue surfaces together, and moving a retaining element coupled to the flexible member relative to the fixation member. The retaining element acts to limit loosening of the flexible member relative to the fixation member. An apparatus for repairing a tear in soft tissue includes first and second fixation members, a flexible member substantially immovably secured to the first fixation member and movably coupled to the second fixation member, and a retaining element coupled to the flexible member. In another embodiment, an apparatus for repairing a tear in soft tissue includes a fixation member, and a flexible member movably coupled to the fixation member. A first end of the flexible member is loop back and secured to the flexible member.



WO 02/36020 A1

CLOSURE DEVICE AND METHOD FOR TISSUE REPAIR

BACKGROUND

This application is related to co-pending application U.S. Serial No. 09/453,120, filed December 2, 1999, entitled WOUND CLOSURE DEVICES AND METHODS, hereby incorporated herein by reference in its entirety.

5 The invention relates to a closure device and method for tissue repair.

Fibrous tissue wounds, such as muscle, ligament, and cartilage tears, can be repaired arthroscopically using sutures. Traditionally, to close a fibrous tissue wound, a surgeon would insert two suture needles into the tissue with sutures attached, thread the sutures across the wound, and then tie knots to fix the free ends of the sutures within the tissue.

10 To simplify the wound closure procedure and to improve fixation, various types of suture anchors have been developed. One example of a suture anchor is disclosed in Hayhurst, U.S. Patent No. 4,741,330, which is incorporated herein by reference. In Hayhurst, one end of a suture is fixed to a resiliently-deformable, bar-shaped suture anchor. The anchor is loaded into the bore of a hollow needle and deployed into or against the fibrous
15 tissue. The surgeon then threads the suture across the wound and tensions a free end of the suture to pull the wound closed. When the surgeon tensions the suture, the bar in the anchor becomes oriented transversely to the suture hole, anchoring the suture in place.

SUMMARY

20 According to one aspect of the invention, a surgical method includes positioning a fixation member relative to tissue, moving a flexible member coupled to the fixation member relative to the fixation member to bring two tissue surfaces together, and moving a retaining element coupled to the flexible member relative to the fixation member. The retaining element acts to limit loosening of the flexible member relative to the fixation member.

25 Embodiments of this aspect of the invention may include one or more of the following features.

The step of moving the flexible member comprises pulling the flexible member. The step of moving the flexible member also accomplishes the step of moving the retaining

secured to the first fixation member and movably coupled to the second fixation member, and a retaining element coupled to the flexible member. The retaining element is movable relative to the second fixation member and acts to limit loosening of the flexible member relative to the fixation member.

5 According to another aspect of the invention, an apparatus for repairing a tear in soft tissue includes at least two fixation members, a flexible member substantially immovably secured to the first fixation member and movably coupled to the second fixation member, and a retaining element coupled to the flexible member. The retaining element is slidably received by the flexible member and acts to limit loosening of the flexible member relative to
10 the fixation member.

 According to another aspect of the invention, an apparatus for repairing a tear in soft tissue includes a fixation member, and a flexible member movably coupled to the fixation member. A first end of the flexible member is looped back and secured to the flexible member to form a loop. The loop is remote from the fixation member.

15 According to another aspect of the invention, a flexible member holder includes a shaft, a first tine at an end region of the shaft defining a first region for receiving a first portion of a loop of a flexible member, and a second tine at the end region of the shaft defining a second region for receiving a second portion of the loop of the flexible member.

 Embodiments of this aspect of the invention may include one or more of the
20 following features. The shaft is a tube. The first and second regions are grooves.

 According to another aspect of the invention, a device for repairing a tear in a tissue includes a needle having a distal region defined between two holding elements, and a proximal region. A first fixation member is positioned within the distal region and a second fixation member is positioned within the proximal region. A flexible member is coupled to
25 the first and second fixation members.

 Embodiments of this aspect of the invention may include one or more of the following features. A first of the holding elements is a crimp in the needle in the distal region, and the second holding element is a dimple or ramp extending into a lumen of the needle. The needle wall has a slot and the fixation members extend through the slot. The
30 needle is sized to fit into an end of a protector tube. A push pin is sized to fit inside the needle.

FIG. 5A is a side view of a variable length depth stop for use with the delivery device of FIG. 3;

FIG. 5B is a perspective view of a cannula for use with the delivery device of FIG. 3;

FIGS. 6-11 show the delivery device in use inserting the closure device of FIG. 1 in soft tissue, with FIG. 7 being an exploded view of region 7 of FIG. 6;

FIG. 12 is an illustration of the closure device of FIG. 1 with an alternative embodiment of a retaining element, shown mending a tear in soft tissue;

FIGS. 12A and 12B show alternative embodiments of the retaining element of FIG. 11;

FIG. 12C shows the retaining element of FIG. 12 in an alternative position;

FIG. 13 shows an additional alternative embodiment of a retaining element in the form of an overhand knot;

FIGS. 13A and 13B show an overhand knot and a knot pusher for advancing the overhand knot of FIG. 13;

FIG. 14 is an illustration of an alternative embodiment of a closure device;

FIG. 14A shows an alternative arrangement of the closure device and delivery device of FIG. 4;

FIG. 14B is an illustration of an alternative embodiment of a closure device;

FIG. 15 is an illustration of an alternative embodiment of a closure device for use in attaching soft tissue to bone;

FIG. 16 is a cross-sectional side view of an alternative embodiment of a closure device, shown mending a tear in soft tissue;

FIG. 17 shows the closure device of FIG. 16 in use prior to securing the closure device in place;

FIG. 18 is a top view of the closure device of FIG. 16, shown after securing the closure device in place;

FIG. 19 is a side view of a delivery device for inserting the closure device of FIG. 16 in soft tissue;

FIG. 19A is a perspective view of a distal section of the delivery device of FIG. 19 shown with a fixation member of the closure device of FIG. 16;

tension on suture 10 to pull suture 10 in the opposite direction, which would allow tear 12 to re-open.

Referring to FIGS. 2A - 2I, prior to insertion into tissue 14, suture 10 is attached to fixation members 16, 18 and slip knot 28 is formed. Fixation member 16 defines holes 16a, 16b for receiving suture 10, and fixation member 18 defines holes 18a, 18b for receiving suture 10. As illustrated in FIGS. 2A-2D, suture 10 is attached to fixation member 16 by threading suture 10 through a needle 50, and passing needle 50 and suture 10 through holes 16a, 16b in fixation member 16 (FIG. 2A). Suture 10 now defines a long suture section 52 and a short suture section 54. Long suture section 52 is then attached to short suture section 54 by passing needle 50 and long suture section 52 through short suture section 54 at a region 56 (FIG. 2B). Pulling long suture section 52 away from fixation member 16 (FIG. 2C) then draws region 56 toward fixation member 16 forming a knot 60 (FIG. 2D). Suture 10 is now secured to fixation member 16.

Referring to FIGS. 2E-2I, suture 10 is now attached to fixation member 18 by passing long suture section 52 through holes 18a, 18b in second fixation member 18 (FIG. 2E). Long suture section 52 now defines a first suture length 62 and second suture length 64. Slip knot 28 is formed by passing fixation member 16 under suture length 64, over suture length 64, and under suture length 62, forming a loop 66 (FIG. 2F); then passing fixation member 16 over suture lengths 62 and 64, forming a loop 68 (FIG. 2G); and then passing fixation member 16 under suture lengths 64 and 62 (FIG. 2G), and finally through loop 68 (FIG. 2H). Pulling fixation member 16 relative to fixation member 18 tightens slip knot 28 (FIG. 2I). Pulling free end 30 of suture 10 now acts to slide suture 10 through slip knot 28, while slip knot 28 limits sliding of suture 10 in the opposite direction when suture 10 is under tension.

Referring to FIG. 3, a delivery device 99 for implanting device 8 in tissue 14 includes a sheath 200 and a needle 100. Sheath 200 is preferably formed from plastic, and needle 100 is preferably metal. Needle 100 has an open distal end 111 with a pointed, tissue piercing tip 108. Needle 100 has an inner surface 102 defining a lumen 104 and a slot 110 both extending to open distal end 111. Slot 110 extends from an outer surface 106 of needle 100 to lumen 102. As described further below, needle 100 receives fixation member 16 and 18 within lumen 104 and slot 110 with suture 10 tied to fixation members 16, 18 as illustrated in FIGS. 2A-2I. Sheath 200 defines a lumen 202 which receives needle 100 and device 8 with

needle 100, as described above, sheath 200 is placed over needle 100, with the majority of suture 10 located within and protected by sheath 200. Sheath 200 also covers the majority of fixation member 18 and helps keep fixation member 18 in position. Sheath 200 is then secured to handle 180 by an interference fit. The distance needle 100 extends from sheath 200 determines the penetration depth of needle 100 into the tissue. Delivery device 99 is supplied to the surgeon with device 8 pre-loaded in needle 100.

Referring to FIG. 5A, an outer protective tube 200a can be placed over sheath 200. Tube 200a protects the needle tip during shipping. If it is desired to supply the surgeon with a variable length depth stop, tube 200a can be provided with gradations 201. The surgeon scores tube 200a to provide the tube with the desired length for the surgical procedure. Tube 200a is coupled to handle 190 by a loose interference fit to allow the surgeon to remove tube 200a if tube 200a is not being used during surgery.

Referring to FIG. 5B, to eliminate the need for placement of delivery device 99 through an arthroscopy cannula, a removable cannula 202a, formed, for example, of a plastic material, can be placed over sheath 200. Cannula 202a has a distal, tissue penetrating tip 203a and a slot 204a extending from a proximal end 205a of cannula 202a to within about 0.02 inches of distal tip 203a to define a distal region 206a. Slot 204a permits the removal of cannula 202a from delivery device 99 after placement of the delivery device in the joint. To remove cannula 202a, the surgeon grasps the cannula and moves it laterally relative to sheath 200, until sheath 200 slides through slot 204a. The surgeon then pulls cannula 202a proximally, which breaks cannula region 206a, permitting complete removal of cannula 202a.

Referring to FIGS. 6-11, in use, preferably under arthroscopic guidance, the user inserts delivery device 99 into, for example, the knee joint, and passes needle 100 through soft tissue 14 and across tear 12, until needle tip 108 and fixation member 16 extend through tissue surface 20. Dimple 130 prevents fixation member 16 from sliding proximally in response to forces acting on fixation member 16 during insertion through tissue 14. Fixation member 16 is now positioned with flat, tissue facing surface 154a of portion 154 of fin 152 extending beyond needle surface 106 engaging tissue surface 20 (FIG. 7). The user then pulls delivery device 99 proximally removing needle 100 from tissue 14 (FIG. 8). The force of the engagement of fixation member 16 with tissue surface 20 during removal of needle

element 210 is positioned on free end 30 of suture 10. While pulling on free end 30, the surgeon advances retaining element 210 through tissue 14, in the direction of arrow 212, until retaining element 210 is positioned against fixation member 18, as shown in dashed line. This action acts to close tear 12 and secure device 8 in place.

5 Retaining element 210 defines a through bore 216 for receiving suture 10. The material of retaining element 210, e.g., acetal, is selected, and the diameter of through bore 216 is sized relative to suture 10 to provide the desired amount of friction between suture 10 and retaining element 210 for adequate securement. Thus, the user can slide suture 10 in the direction of arrow 212, but adequate friction is provided between suture 10 and retaining
10 element 210 to limit sliding of retaining element 210 in the opposite direction under normal loads in the knee joint.

Referring to FIG. 12A, a retaining element 210a defines two angled channels 218, 220 for receiving free end 30 of suture 10. Retaining element 210a has a generally cylindrical surface 221 and ends 222, 223. Channel 218 has a first opening 224 at end 222
15 and second opening 225 on surface 221. Channel 220 has a first opening 226 at end 223 and a second opening 227 on the same side of surface 221 as channel 218. Suture 10 follows a tortuous path through channel 218, over surface 221 between openings 225 and 227, and then through channel 220 with free end 30 extending from opening 226. The tortuous path aids in securement of device 8.

20 In FIG. 12B, rather the channel opening on surface 221 being on the same side, a retaining element 210b defines two angled channels 218a, 220a each having a channel end 225a, 227a, respectively, on opposite sides of surface 221. Suture 10 thus wraps part way around element 210b to aid in securement of device 8.

Referring to FIG. 12C, rather than positioning the retaining element on suture 10 after
25 suture 10 exits from fixation member 18, here retaining element 210, 210a, or 210b is positioned along suture 10 between the portions of suture 10 passing through fixation member 18.

Retaining elements 210, 210a, 210b are slidably received on suture 10. In the
embodiments of FIGS. 12-12B, the retaining element slides over suture 10, changing position
30 relative to fixation member 18, while in the embodiment of FIG. 12C, suture 10 slides within

for passage therethrough by push rod 170. Push rod 170 preferably is biased off angle such that when push rod 170 is pulled out of the passage in fixation member 18a, the push rod is no longer aligned with the passage. Subsequent advancement of push rod 170 then engages an end face of fixation member 18a to push the fixation member toward the tip of the needle 100, rather than back through the passage. Slider 190 is preferably spring loaded such that after fixation member 18 is pushed out of needle 100, push rod 170 springs back to engage the next fixation member 18a.

Referring to FIG. 14A, the positions of fixation member 16 and 18 in needle 100 can be swapped, with fixation member 18 located in distal region 112 such that fixation member 18 is implanted in the tissue prior to implantation of fixation member 16. Referring to FIG. 14B, rather than suture 10 being fixed to fixation member 16, here suture 10 is attached to fixation member 16 the same as the attachment to fixation member 18, such that a second slip knot 28a is formed and a second free end 30a of suture extends from fixation member 16. To secure fixation members 16 and 18, both ends 30 and 30a of suture 10 are pulled.

Referring to FIG. 15, in an application for securing soft tissue 262 to bone 264, a suture 266 is attached to fixation members in the form of a first anchor member 270 and a second anchor member 272. Members 270, 272 are, for example, TAG WEDGE bone anchors available from Smith & Nephew, Inc. Endoscopy Division, Andover, MA. Other bone anchors known in the art can be employed. Suture 266 has a first end 274 fixed to anchor member 270, a second free end 276, and a slip knot 268, formed as described above for slip knot 28. Suture 266 preferably passes through a separate suture loop 278, rather than through 272 itself. Suture loop 278 acts as a good pulley allowing suture 266 to slide relative to suture loop 278.

In use, the user forms bone holes 280, 282 in bone 264. The user then implants anchor member 270 in bone hole 280, with suture 266 already threaded as shown, followed by implanting anchor member 272 in bone hole 282. The user then pulls on free end 276 of suture 266, which brings soft tissue 262 against bone 264. Slip knot 268 limits loosening of suture 266. By using suture loop 278, suture 266 is not located within bone hole 282 in use thus limiting the possibility of trapping suture 266 against wall 284 of bone hole 282. If suture 266 were trapped in bone hole 282, pulling free end 276 of suture 266 would not result

Referring to FIG. 20, in use, the user inserts distal portion 430 of suture holder 400 into tear 12 of tissue 14, and then advances needle 460 through tissue 14, traversing tear 12, and exiting tissue 14 at tissue surface 20. Needle 460 passes between tines 440 and 450, and thus through looped end 316 of suture 310 (FIG. 21). The user then retracts needle 460 from tissue 14 (FIG. 22). The contact of fastening member 326 with tissue surface 20 during the retraction of needle 460 acts to push fastening member 326 out of needle 460 such that fastening member 326 remains at surface 20, as described above with reference to FIG. 7. Pulling on free end 334 of suture 310 brings sides 22, 24 of tear 12 into juxtaposition. Slip knot 321 secures device 308 in place. Excess suture 310 can then be cut off.

Referring to FIG. 23, rather than securing device 308 with a slip knot, suture 310 includes a retaining element in the form of a Chinese trap or hand cuff 495, that is, an element that when pulled on, tightens around something disposed within the element. Free end 334 of suture 310 is slidably received within trap 495. When free end 334 of suture 310 is pulled in the direction of arrow 520 trap 495 is stretched, eventually gripping suture passing therethrough to secure suture 310 and device 308. The retaining element can also take the form of retaining elements described above with reference to FIGS. 12-12C and 13.

Referring to FIG. 24, a device 799 for repairing tear 12 in tissue 14 includes a barbed fastening member 800 and a suture 820. Suture 820 has an end 810 attached to fastening member 800. Suture 820 is formed in loop 830 with a second end 832 of suture 820 attached to suture 820. Delivery device 399 can be used to deploy device 799 with suture 820 being tightened to close tear 12 by pushing fastening member 800 in the direction of arrow 840, rather than pulling on a free end of suture. Barbed fastening member 800 limits loosening of suture 820.

Referring to FIG. 25, an alternative embodiment of a fixation member 600, which can be used in any of the above embodiments, includes through bores 610, 620 with radiused corners 615 to reduce friction between suture 470 and fixation member 600. Referring to FIG. 26, another embodiment of a fixation member 650, which can be used in any of the above embodiments, includes a solid rod 660 with ends 680, 690, and a braided suture 670 attached to ends 680, 690. Suture 670 forms a loop 700 for receiving suture 10 or suture 310. Loop 700 lines up with suture 10, 310 to act as a pulley and reducing friction between the suture and fixation member.

WHAT IS CLAIMED IS:

- 1 1. A surgical method, comprising:
2 positioning a fixation member relative to tissue,
3 moving a flexible member coupled to the fixation member relative to the fixation
4 member to bring two tissue surfaces together, and
5 moving a retaining element coupled to the flexible member relative to the fixation
6 member, the retaining element acting to limit loosening of the flexible member relative to the
7 fixation member.
- 1 2. The surgical method of claim 1 wherein the step of moving the flexible member
2 comprises pulling the flexible member.
- 1 3. The surgical method of claim 1 wherein the step of moving the flexible member also
2 accomplishes the step of moving the retaining element.
- 1 4. The surgical method of claim 3 further comprising providing the retaining element in
2 the form of a slip knot.
- 1 5. The surgical method of claim 1 wherein the step of moving the retaining element
2 includes moving the retaining element relative to the flexible element.
- 1 6. The surgical method of claim 5 further comprising providing the retaining element in
2 the form of a friction element which permits sliding of the retaining element relative to the
3 flexible element in only one direction.
- 1 7. The surgical method of claim 1 further comprising providing the retaining element in
2 the form of an overhand knot.
- 1 8. The surgical method of claim 7 further comprising advancing the overhand knot
2 along the flexible element.

1 19. The surgical method of claim 18 further comprising positioning the loop within a tear
2 in soft tissue.

1 20. A method for repairing a tear in soft tissue, comprising:
2 advancing a fixation member coupled to a flexible member through tissue on either side
3 of the tear and through a loop of the flexible member, and
4 tensioning the flexible member to bring two tissue surfaces on either side of the tear
5 together.

1 21. The method of claim 20 further comprising positioning the loop within the tear.

1 22. The method of claim 20 further comprising pulling an end of the flexible member to
2 bring the two tissue surfaces together.

1 23. The method of claim 20 further comprising providing the fixation member in the
2 form of a barbed member.

1 24. An apparatus for repairing a tear in soft tissue, comprising:
2 at least two fixation members,
3 a flexible member substantially immovably secured to a first of the fixation members and
4 movably coupled to a second of the fixation members, and
5 a retaining element coupled to the flexible member, the retaining element being movable
6 relative to the second fixation member and acting to limit loosening of the flexible member
7 relative to the second fixation member.

1 25. An apparatus for repairing a tear in soft tissue, comprising:
2 at least two fixation members,
3 a flexible member substantially immovably secured to a first of the fixation members and
4 movably coupled to a second of the fixation members, and
5 a retaining element coupled to the flexible member, the retaining element being slidably
6 received by the flexible member and acting to limit loosening of the flexible member relative
7 to the second fixation member.

1 33. The device of claim 30 wherein one of the holding elements comprises a ramp
2 extending into a lumen of the needle.

1 34. The device of claim 30 wherein the needle defines a slot through a wall of the needle,
2 the first and second fixation members extending through the slot.

1 35. The device of claim 30 further comprising a protector tube, the tube defining a bore,
2 wherein the needle is sized to fit into an end of the protector tube.

1 36. The device of claim 30 further comprising a push pin, the pin being sized to fit inside
2 the needle.

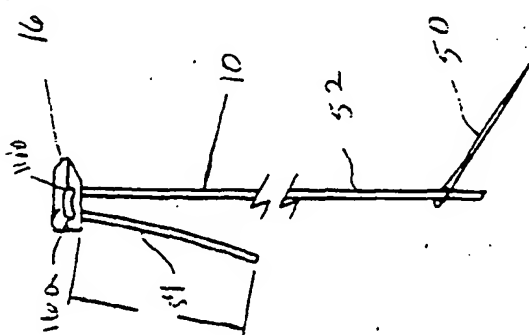


FIG. 2A

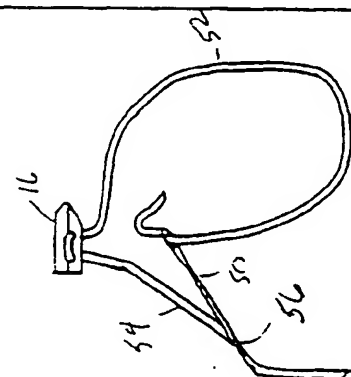


FIG. 2B



FIG. 2C

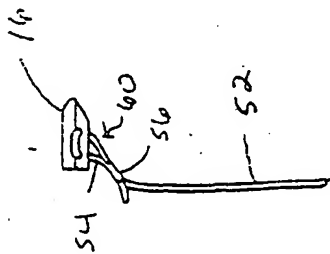


FIG. 2D

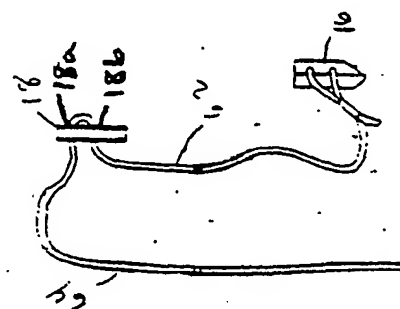


FIG. 3A

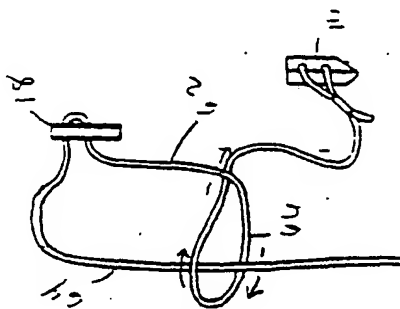


FIG. 3B

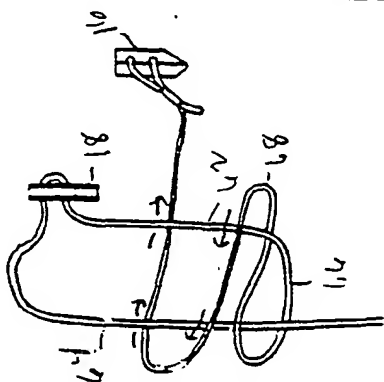


FIG. 3C

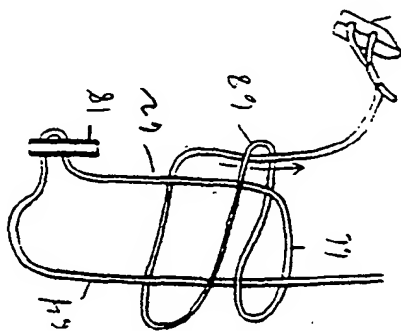


FIG. 3D

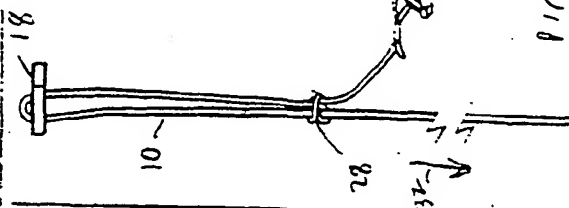
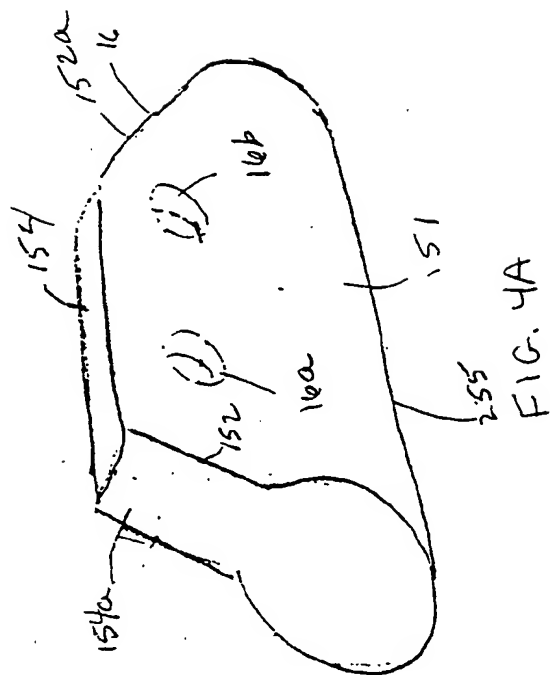
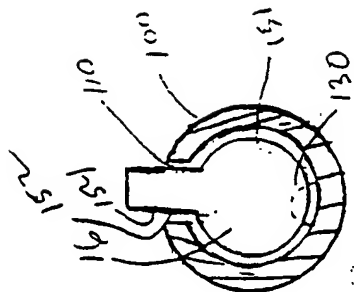
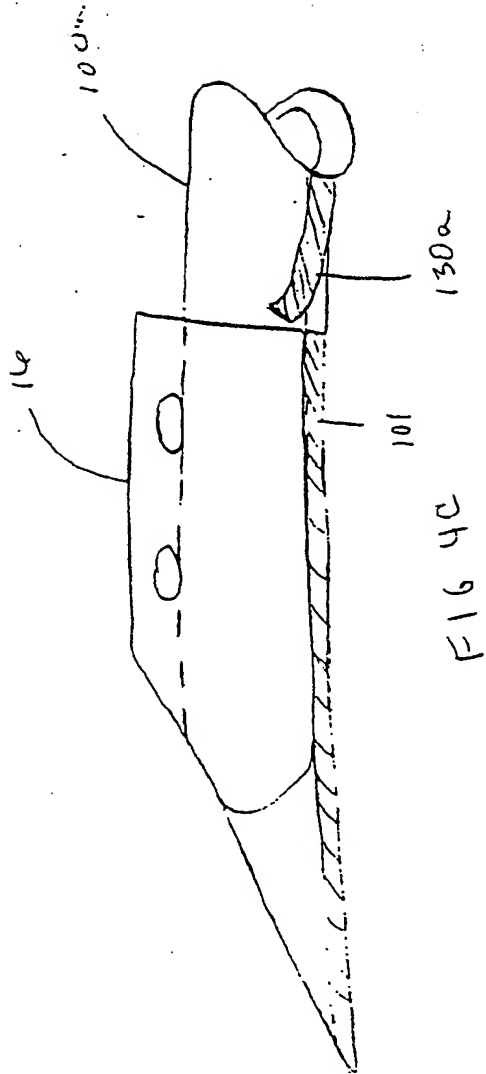


FIG. 3E



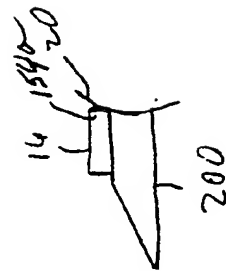
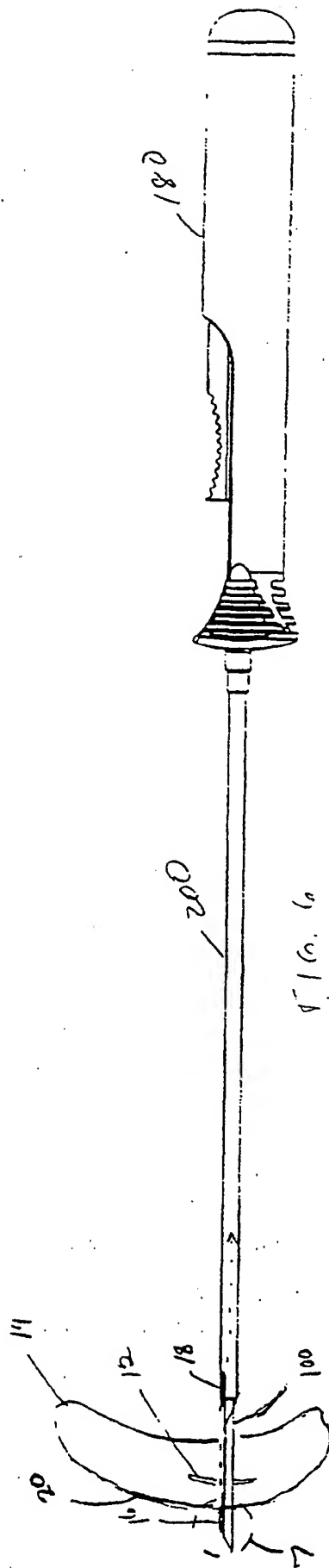
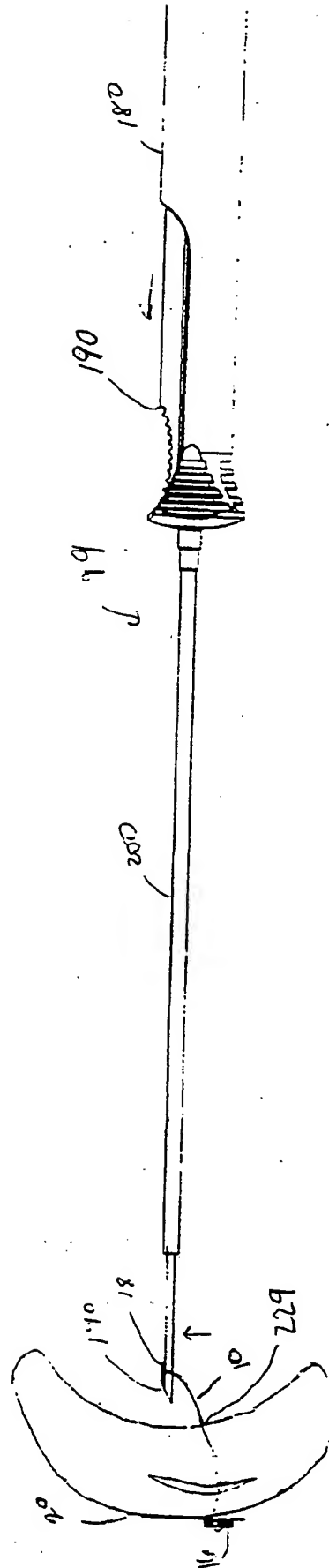
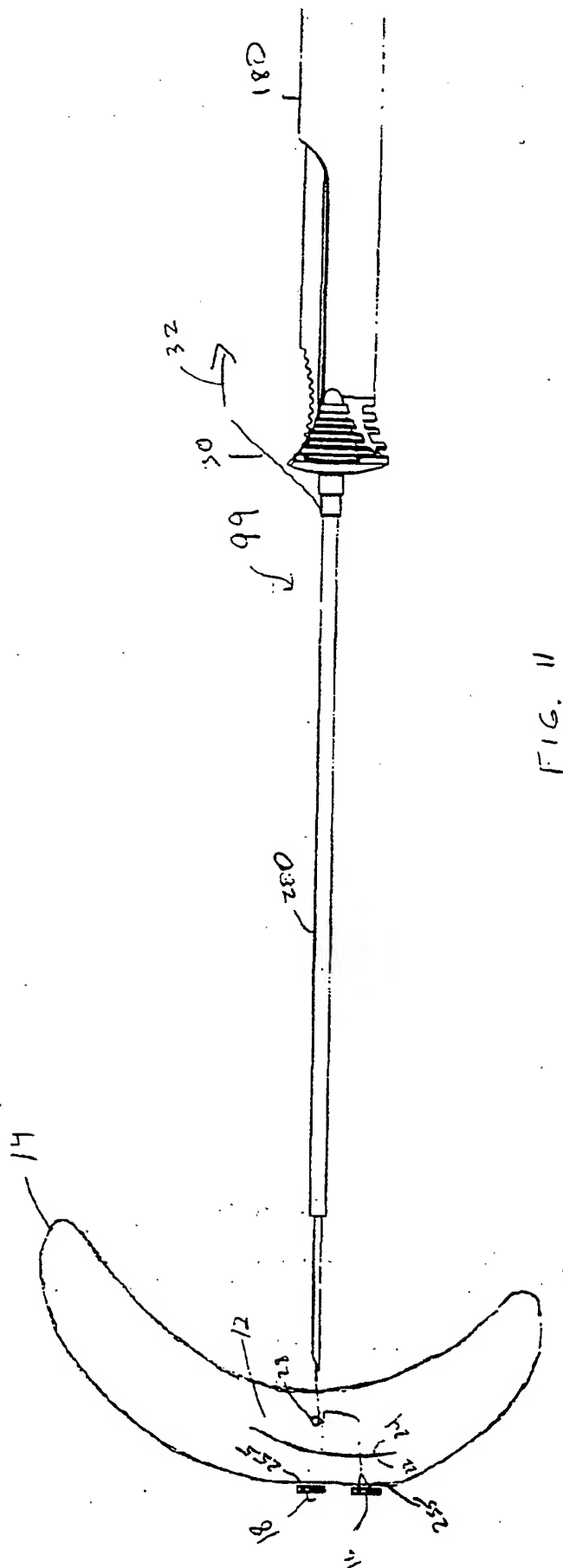
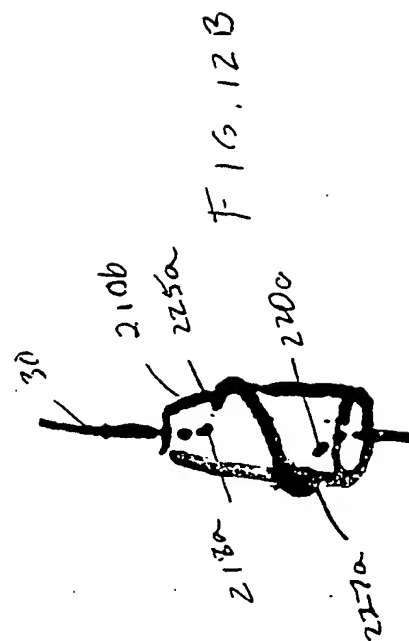
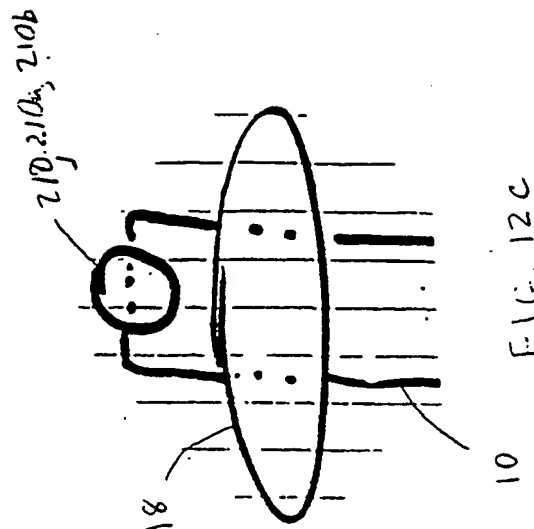
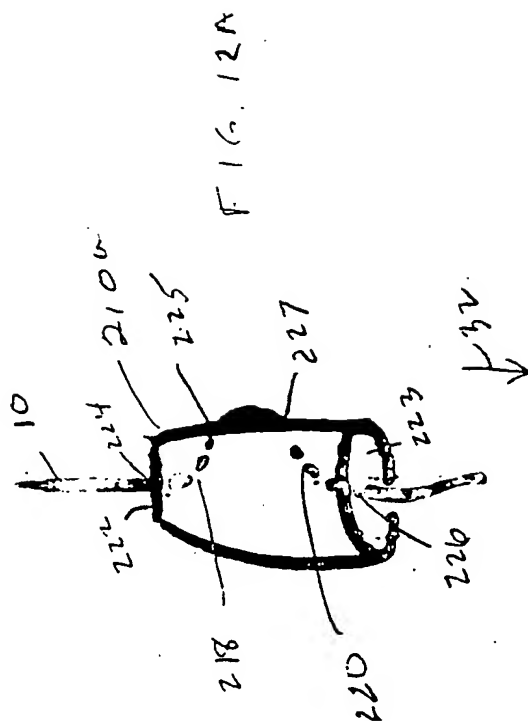


FIG. 7







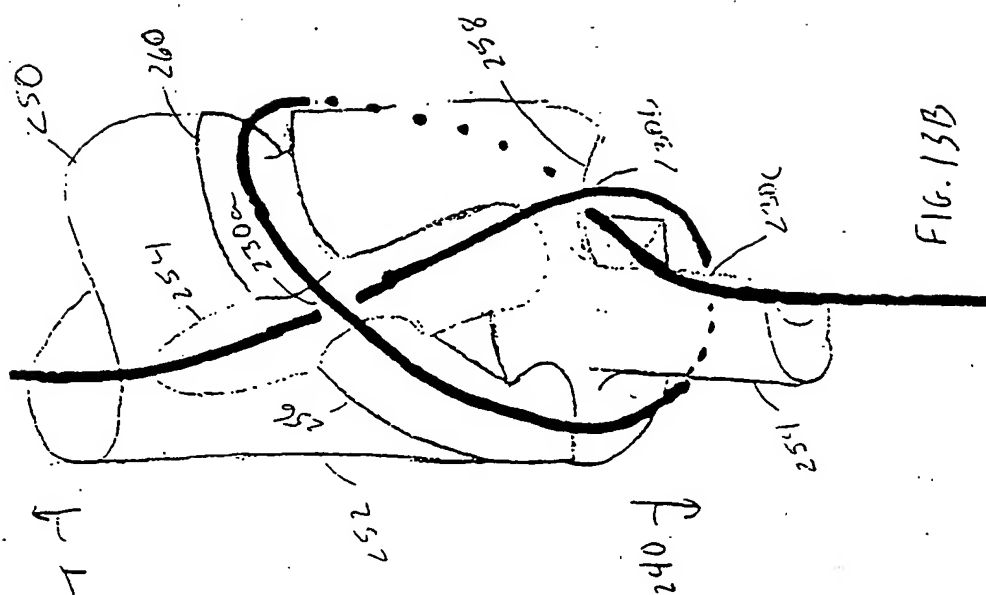


FIG. 13B

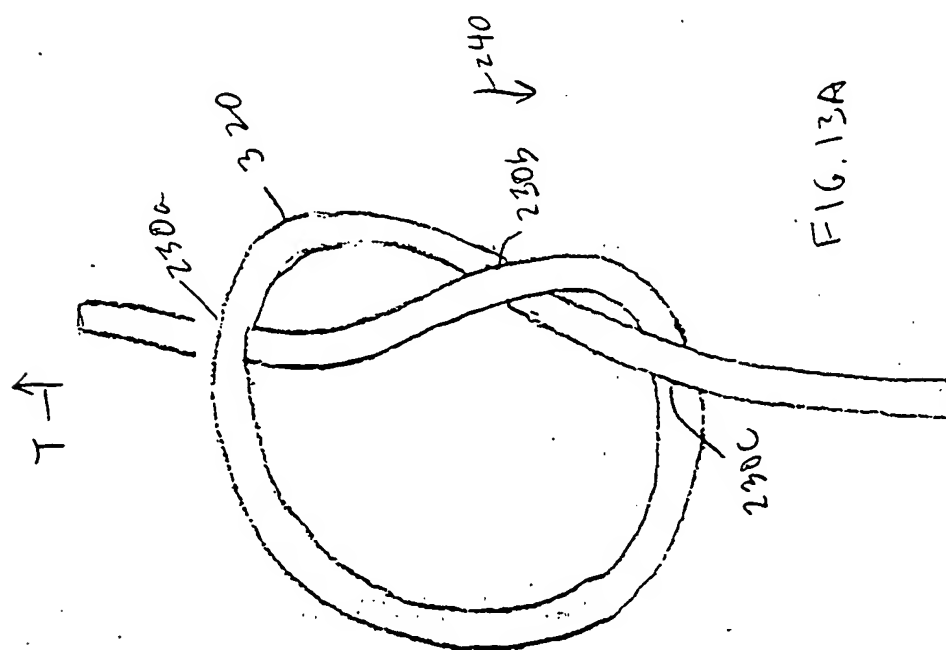


FIG. 13A

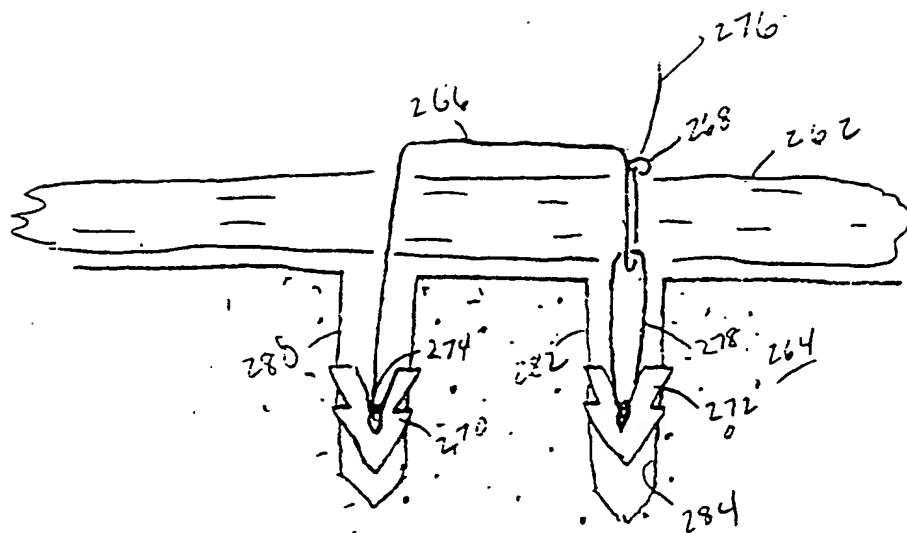
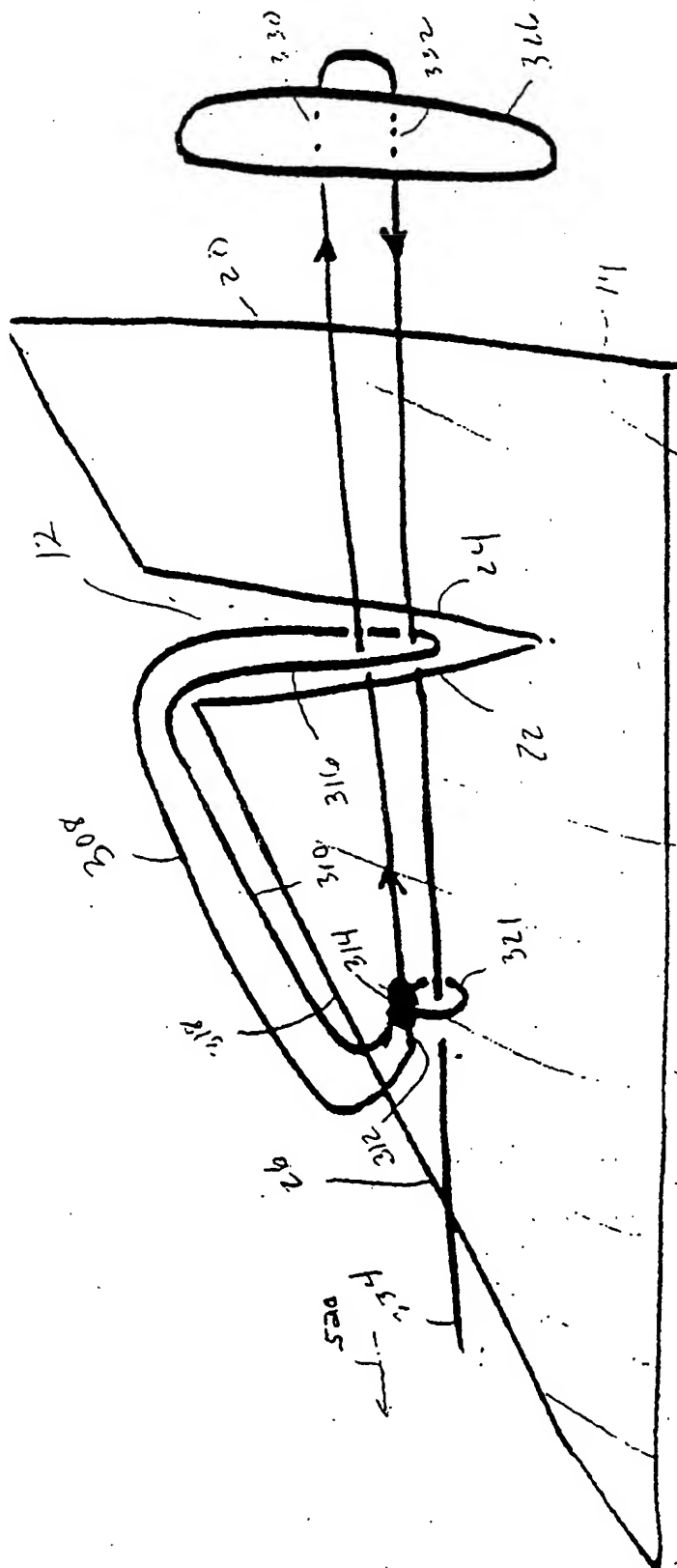
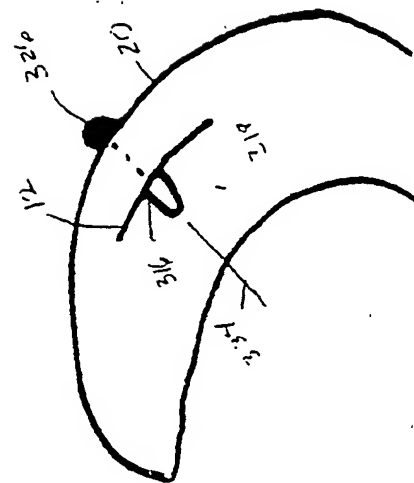


FIG. 15



File 17



15.18

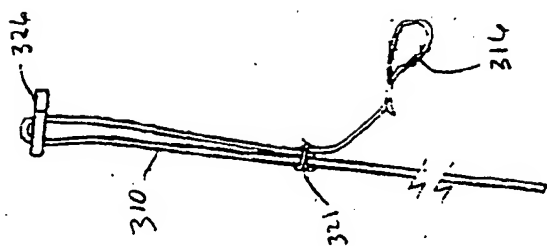


FIG. 19C

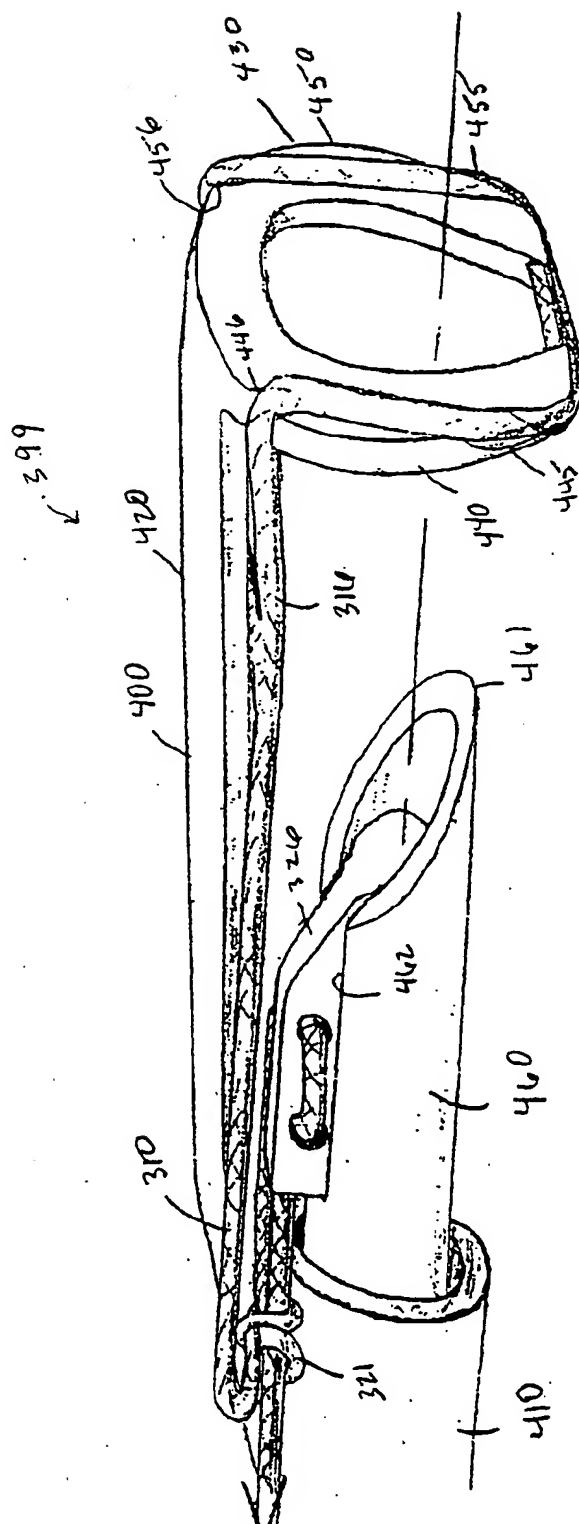
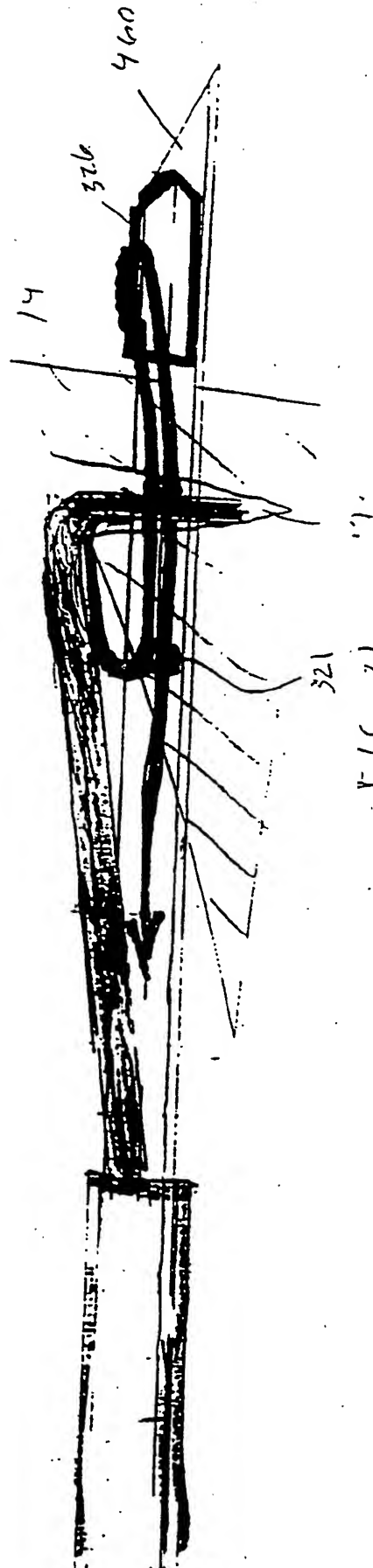


FIG. 19B



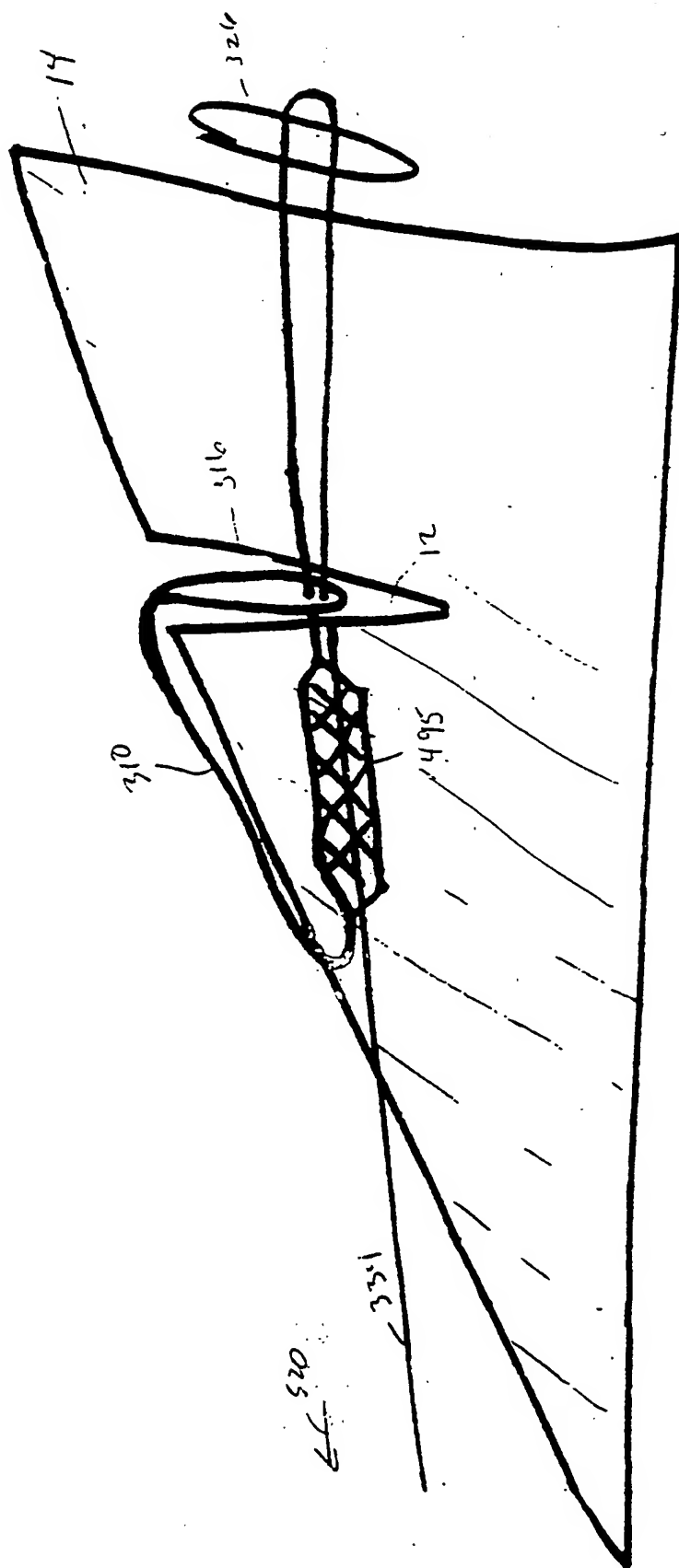


FIG. 23

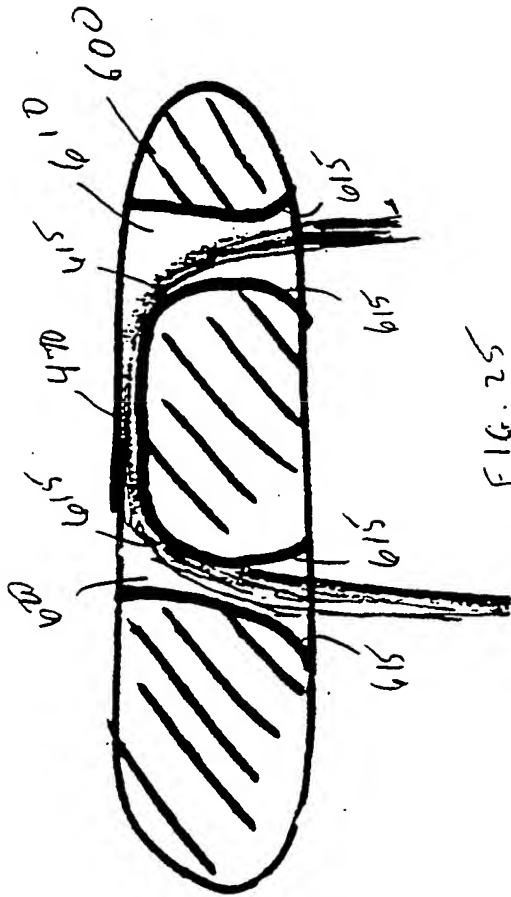


FIG. 25

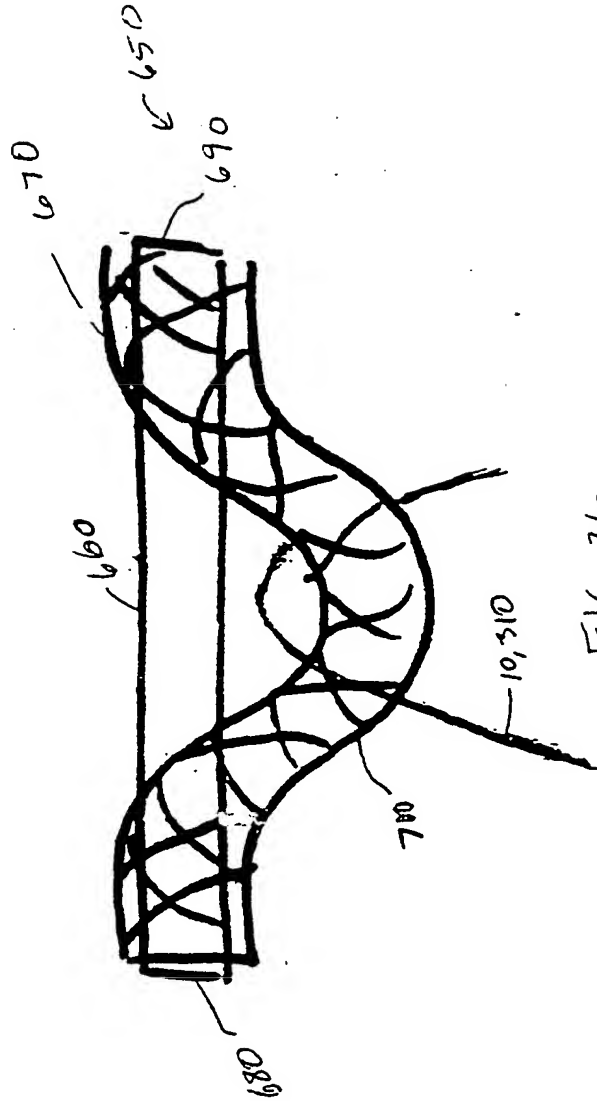


FIG. 26

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 01/32625

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No. .
X	US 3 910 281 A (KLETSCHKA ET AL.) 7 October 1975 (1975-10-07) abstract; figures ---	26
P,X	WO 01 39671 A (SMITH & NEPHEW, INC.) 7 June 2001 (2001-06-07) the whole document -----	24-36

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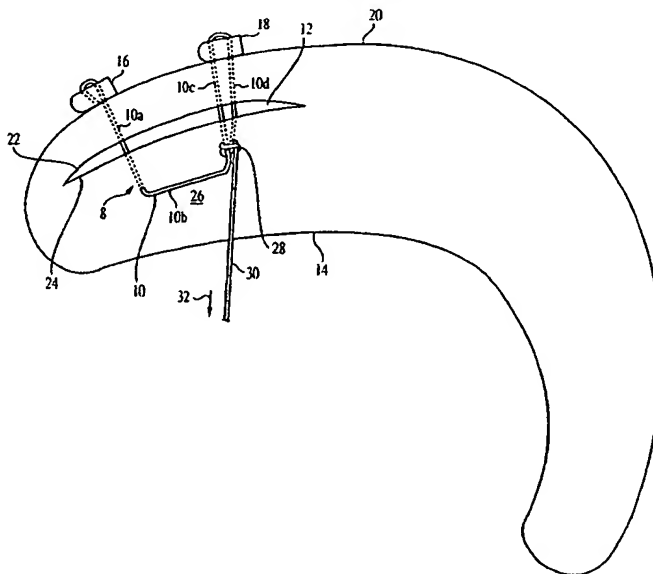
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(54) Title: CLOSURE DEVICE AND METHOD FOR TISSUE REPAIR



(57) Abstract: A surgical method includes positioning a fixation member relative to tissue, moving a flexible member coupled to the fixation member relative to the fixation member to bring two tissue surfaces together, and moving a retaining element coupled to the flexible member relative to the fixation member. The retaining element acts to limit loosening of the flexible member relative to the fixation member. An apparatus for repairing a tear in soft tissue includes first and second fixation members, a flexible member substantially immovably secured to the first fixation member and movably coupled to the second fixation member, and a retaining element coupled to the flexible member. In another embodiment, an apparatus for repairing a tear in soft tissue includes a fixation member, and a flexible member movably coupled to the fixation member. A first end of the flexible member is loop back and secured to the flexible member.

WO 02/036020 A1

CLOSURE DEVICE AND METHOD FOR TISSUE REPAIR

BACKGROUND

This application is related to co-pending application U.S. Serial No. 09/453,120, filed December 2, 1999, entitled WOUND CLOSURE DEVICES AND METHODS, hereby incorporated herein by reference in its entirety.

5 The invention relates to a closure device and method for tissue repair.

Fibrous tissue wounds, such as muscle, ligament, and cartilage tears, can be repaired arthroscopically using sutures. Traditionally, to close a fibrous tissue wound, a surgeon would insert two suture needles into the tissue with sutures attached, thread the sutures across the wound, and then tie knots to fix the free ends of the sutures within the tissue.

10 To simplify the wound closure procedure and to improve fixation, various types of suture anchors have been developed. One example of a suture anchor is disclosed in Hayhurst, U.S. Patent No. 4,741,330, which is incorporated herein by reference. In Hayhurst, one end of a suture is fixed to a resiliently-deformable, bar-shaped suture anchor. The anchor is loaded into the bore of a hollow needle and deployed into or against the fibrous
15 tissue. The surgeon then threads the suture across the wound and tensions a free end of the suture to pull the wound closed. When the surgeon tensions the suture, the bar in the anchor becomes oriented transversely to the suture hole, anchoring the suture in place.

SUMMARY

20 According to one aspect of the invention, a surgical method includes positioning a fixation member relative to tissue, moving a flexible member coupled to the fixation member relative to the fixation member to bring two tissue surfaces together, and moving a retaining element coupled to the flexible member relative to the fixation member. The retaining element acts to limit loosening of the flexible member relative to the fixation member.

25 Embodiments of this aspect of the invention may include one or more of the following features.

The step of moving the flexible member comprises pulling the flexible member. The step of moving the flexible member also accomplishes the step of moving the retaining

secured to the first fixation member and movably coupled to the second fixation member, and a retaining element coupled to the flexible member. The retaining element is movable relative to the second fixation member and acts to limit loosening of the flexible member relative to the fixation member.

5 According to another aspect of the invention, an apparatus for repairing a tear in soft tissue includes at least two fixation members, a flexible member substantially immovably secured to the first fixation member and movably coupled to the second fixation member, and a retaining element coupled to the flexible member. The retaining element is slidably received by the flexible member and acts to limit loosening of the flexible member relative to
10 the fixation member.

 According to another aspect of the invention, an apparatus for repairing a tear in soft tissue includes a fixation member, and a flexible member movably coupled to the fixation member. A first end of the flexible member is looped back and secured to the flexible member to form a loop. The loop is remote from the fixation member.

15 According to another aspect of the invention, a flexible member holder includes a shaft, a first tine at an end region of the shaft defining a first region for receiving a first portion of a loop of a flexible member, and a second tine at the end region of the shaft defining a second region for receiving a second portion of the loop of the flexible member.

 Embodiments of this aspect of the invention may include one or more of the
20 following features. The shaft is a tube. The first and second regions are grooves.

 According to another aspect of the invention, a device for repairing a tear in a tissue includes a needle having a distal region defined between two holding elements, and a proximal region. A first fixation member is positioned within the distal region and a second fixation member is positioned within the proximal region. A flexible member is coupled to
25 the first and second fixation members.

 Embodiments of this aspect of the invention may include one or more of the following features. A first of the holding elements is a crimp in the needle in the distal region, and the second holding element is a dimple or ramp extending into a lumen of the needle. The needle wall has a slot and the fixation members extend through the slot. The
30 needle is sized to fit into an end of a protector tube. A push pin is sized to fit inside the needle.

FIG. 5A is a side view of a variable length depth stop for use with the delivery device of FIG. 3;

FIG. 5B is a perspective view of a cannula for use with the delivery device of FIG. 3;

FIGS. 6-11 show the delivery device in use inserting the closure device of FIG. 1 in soft tissue, with FIG. 7 being an exploded view of region 7 of FIG. 6;

FIG. 12 is an illustration of the closure device of FIG. 1 with an alternative embodiment of a retaining element, shown mending a tear in soft tissue;

FIGS. 12A and 12B show alternative embodiments of the retaining element of FIG. 12;

FIG. 12C shows the retaining element of FIG. 12 in an alternative position;

FIG. 13 shows an additional alternative embodiment of a retaining element in the form of an overhand knot;

FIGS. 13A and 13B show an overhand knot and a knot pusher for advancing the overhand knot of FIG. 13;

FIG. 14 is an illustration of an alternative embodiment of a closure device;

FIG. 14A shows an alternative arrangement of the closure device and delivery device of FIG. 4;

FIG. 14B is an illustration of an alternative embodiment of a closure device;

FIG. 15 is an illustration of an alternative embodiment of a closure device for use in attaching soft tissue to bone;

FIG. 16 is a cross-sectional side view of an alternative embodiment of a closure device, shown mending a tear in soft tissue;

FIG. 17 shows the closure device of FIG. 16 in use prior to securing the closure device in place;

FIG. 18 is a top view of the closure device of FIG. 16, shown after securing the closure device in place;

FIG. 19 is a side view of a delivery device for inserting the closure device of FIG. 16 in soft tissue;

FIG. 19A is a perspective view of a distal section of the delivery device of FIG. 19 shown with a fixation member of the closure device of FIG. 16;

tension on suture 10 to pull suture 10 in the opposite direction, which would allow tear 12 to re-open.

Referring to FIGS. 2A - 2I, prior to insertion into tissue 14, suture 10 is attached to fixation members 16, 18 and slip knot 28 is formed. Fixation member 16 defines holes 16a, 16b for receiving suture 10, and fixation member 18 defines holes 18a, 18b for receiving suture 10. As illustrated in FIGS. 2A-2D, suture 10 is attached to fixation member 16 by threading suture 10 through a needle 50, and passing needle 50 and suture 10 through holes 16a, 16b in fixation member 16 (FIG. 2A). Suture 10 now defines a long suture section 52 and a short suture section 54. Long suture section 52 is then attached to short suture section 54 by passing needle 50 and long suture section 52 through short suture section 54 at a region 56 (FIG. 2B). Pulling long suture section 52 away from fixation member 16 (FIG. 2C) then draws region 56 toward fixation member 16 forming a knot 60 (FIG. 2D). Suture 10 is now secured to fixation member 16.

Referring to FIGS. 2E-2I, suture 10 is now attached to fixation member 18 by passing long suture section 52 through holes 18a, 18b in second fixation member 18 (FIG. 2E). Long suture section 52 now defines a first suture length 62 and second suture length 64. Slip knot 28 is formed by passing fixation member 16 under suture length 64, over suture length 64, and under suture length 62, forming a loop 66 (FIG. 2F); then passing fixation member 16 over suture lengths 62 and 64, forming a loop 68 (FIG. 2G); and then passing fixation member 16 under suture lengths 64 and 62 (FIG. 2G), and finally through loop 68 (FIG. 2H). Pulling fixation member 16 relative to fixation member 18 tightens slip knot 28 (FIG. 2I). Pulling free end 30 of suture 10 now acts to slide suture 10 through slip knot 28, while slip knot 28 limits sliding of suture 10 in the opposite direction when suture 10 is under tension.

Referring to FIG. 3, a delivery device 99 for implanting device 8 in tissue 14 includes a sheath 200 and a needle 100. Sheath 200 is preferably formed from plastic, and needle 100 is preferably metal. Needle 100 has an open distal end 111 with a pointed, tissue piercing tip 108. Needle 100 has an inner surface 102 defining a lumen 104 and a slot 110 both extending to open distal end 111. Slot 110 extends from an outer surface 106 of needle 100 to lumen 102. As described further below, needle 100 receives fixation member 16 and 18 within lumen 104 and slot 110 with suture 10 tied to fixation members 16, 18 as illustrated in FIGS. 2A-2I. Sheath 200 defines a lumen 202 which receives needle 100 and device 8 with

needle 100, as described above, sheath 200 is placed over needle 100, with the majority of suture 10 located within and protected by sheath 200. Sheath 200 also covers the majority of fixation member 18 and helps keep fixation member 18 in position. Sheath 200 is then secured to handle 180 by an interference fit. The distance needle 100 extends from sheath 200 determines the penetration depth of needle 100 into the tissue. Delivery device 99 is supplied to the surgeon with device 8 pre-loaded in needle 100.

Referring to FIG. 5A, an outer protective tube 200a can be placed over sheath 200. Tube 200a protects the needle tip during shipping. If it is desired to supply the surgeon with a variable length depth stop, tube 200a can be provided with gradations 201. The surgeon scores tube 200a to provide the tube with the desired length for the surgical procedure. Tube 200a is coupled to handle 190 by a loose interference fit to allow the surgeon to remove tube 200a if tube 200a is not being used during surgery.

Referring to FIG. 5B, to eliminate the need for placement of delivery device 99 through an arthroscopy cannula, a removable cannula 202a, formed, for example, of a plastic material, can be placed over sheath 200. Cannula 202a has a distal, tissue penetrating tip 203a and a slot 204a extending from a proximal end 205a of cannula 202a to within about 0.02 inches of distal tip 203a to define a distal region 206a. Slot 204a permits the removal of cannula 202a from delivery device 99 after placement of the delivery device in the joint. To remove cannula 202a, the surgeon grasps the cannula and moves it laterally relative to sheath 200, until sheath 200 slides through slot 204a. The surgeon then pulls cannula 202a proximally, which breaks cannula region 206a, permitting complete removal of cannula 202a.

Referring to FIGS. 6-11, in use, preferably under arthroscopic guidance, the user inserts delivery device 99 into, for example, the knee joint, and passes needle 100 through soft tissue 14 and across tear 12, until needle tip 108 and fixation member 16 extend through tissue surface 20. Dimple 130 prevents fixation member 16 from sliding proximally in response to forces acting on fixation member 16 during insertion through tissue 14. Fixation member 16 is now positioned with flat, tissue facing surface 154a of portion 154 of fin 152 extending beyond needle surface 106 engaging tissue surface 20 (FIG. 7). The user then pulls delivery device 99 proximally removing needle 100 from tissue 14 (FIG. 8). The force of the engagement of fixation member 16 with tissue surface 20 during removal of needle

element 210 is positioned on free end 30 of suture 10. While pulling on free end 30, the surgeon advances retaining element 210 through tissue 14, in the direction of arrow 212, until retaining element 210 is positioned against fixation member 18, as shown in dashed line.

This action acts to close tear 12 and secure device 8 in place.

5 Retaining element 210 defines a through bore 216 for receiving suture 10. The material of retaining element 210, e.g., acetal, is selected, and the diameter of through bore 216 is sized relative to suture 10 to provide the desired amount of friction between suture 10 and retaining element 210 for adequate securement. Thus, the user can slide suture 10 in the direction of arrow 212, but adequate friction is provided between suture 10 and retaining
10 element 210 to limit sliding of retaining element 210 in the opposite direction under normal loads in the knee joint.

Referring to FIG. 12A, a retaining element 210a defines two angled channels 218, 220 for receiving free end 30 of suture 10. Retaining element 210a has a generally cylindrical surface 221 and ends 222, 223. Channel 218 has a first opening 224 at end 222
15 and second opening 225 on surface 221. Channel 220 has a first opening 226 at end 223 and a second opening 227 on the same side of surface 221 as channel 218. Suture 10 follows a tortuous path through channel 218, over surface 221 between openings 225 and 227, and then through channel 220 with free end 30 extending from opening 226. The tortuous path aids in securement of device 8.

20 In FIG. 12B, rather the channel opening on surface 221 being on the same side, a retaining element 210b defines two angled channels 218a, 220a each having a channel end 225a, 227a, respectively, on opposite sides of surface 221. Suture 10 thus wraps part way around element 210b to aid in securement of device 8.

Referring to FIG. 12C, rather than positioning the retaining element on suture 10 after suture 10 exits from fixation member 18, here retaining element 210, 210a, or 210b is
25 positioned along suture 10 between the portions of suture 10 passing through fixation member 18.

Retaining elements 210, 210a, 210b are slidably received on suture 10. In the embodiments of FIGS. 12-12B, the retaining element slides over suture 10, changing position
30 relative to fixation member 18, while in the embodiment of FIG. 12C, suture 10 slides within

for passage therethrough by push rod 170. Push rod 170 preferably is biased off angle such that when push rod 170 is pulled out of the passage in fixation member 18a, the push rod is no longer aligned with the passage. Subsequent advancement of push rod 170 then engages an end face of fixation member 18a to push the fixation member toward the tip of the needle 100, rather than back through the passage. Slider 190 is preferably spring loaded such that after fixation member 18 is pushed out of needle 100, push rod 170 springs back to engage the next fixation member 18a.

Referring to FIG. 14A, the positions of fixation member 16 and 18 in needle 100 can be swapped, with fixation member 18 located in distal region 112 such that fixation member 18 is implanted in the tissue prior to implantation of fixation member 16. Referring to FIG. 14B, rather than suture 10 being fixed to fixation member 16, here suture 10 is attached to fixation member 16 the same as the attachment to fixation member 18, such that a second slip knot 28a is formed and a second free end 30a of suture extends from fixation member 16. To secure fixation members 16 and 18, both ends 30 and 30a of suture 10 are pulled.

Referring to FIG. 15, in an application for securing soft tissue 262 to bone 264, a suture 266 is attached to fixation members in the form of a first anchor member 270 and a second anchor member 272. Members 270, 272 are, for example, TAG WEDGE bone anchors available from Smith & Nephew, Inc. Endoscopy Division, Andover, MA. Other bone anchors known in the art can be employed. Suture 266 has a first end 274 fixed to anchor member 270, a second free end 276, and a slip knot 268, formed as described above for slip knot 28. Suture 266 preferably passes through a separate suture loop 278, rather than through 272 itself. Suture loop 278 acts as a good pulley allowing suture 266 to slide relative to suture loop 278.

In use, the user forms bone holes 280, 282 in bone 264. The user then implants anchor member 270 in bone hole 280, with suture 266 already threaded as shown, followed by implanting anchor member 272 in bone hole 282. The user then pulls on free end 276 of suture 266, which brings soft tissue 262 against bone 264. Slip knot 268 limits loosening of suture 266. By using suture loop 278, suture 266 is not located within bone hole 282 in use thus limiting the possibility of trapping suture 266 against wall 284 of bone hole 282. If suture 266 were trapped in bone hole 282, pulling free end 276 of suture 266 would not result

Referring to FIG. 20, in use, the user inserts distal portion 430 of suture holder 400 into tear 12 of tissue 14, and then advances needle 460 through tissue 14, traversing tear 12, and exiting tissue 14 at tissue surface 20. Needle 460 passes between tines 440 and 450, and thus through looped end 316 of suture 310 (FIG. 21). The user then retracts needle 460 from tissue 14 (FIG. 22). The contact of fastening member 326 with tissue surface 20 during the retraction of needle 460 acts to push fastening member 326 out of needle 460 such that fastening member 326 remains at surface 20, as described above with reference to FIG. 7. Pulling on free end 334 of suture 310 brings sides 22, 24 of tear 12 into juxtaposition. Slip knot 321 secures device 308 in place. Excess suture 310 can then be cut off.

Referring to FIG. 23, rather than securing device 308 with a slip knot, suture 310 includes a retaining element in the form of a Chinese trap or hand cuff 495, that is, an element that when pulled on, tightens around something disposed within the element. Free end 334 of suture 310 is slidably received within trap 495. When free end 334 of suture 310 is pulled in the direction of arrow 520 trap 495 is stretched, eventually gripping suture passing therethrough to secure suture 310 and device 308. The retaining element can also take the form of retaining elements described above with reference to FIGS. 12-12C and 13.

Referring to FIG. 24, a device 799 for repairing tear 12 in tissue 14 includes a barbed fastening member 800 and a suture 820. Suture 820 has an end 810 attached to fastening member 800. Suture 820 is formed in loop 830 with a second end 832 of suture 820 attached to suture 820. Delivery device 399 can be used to deploy device 799 with suture 820 being tightened to close tear 12 by pushing fastening member 800 in the direction of arrow 840, rather than pulling on a free end of suture. Barbed fastening member 800 limits loosening of suture 820.

Referring to FIG. 25, an alternative embodiment of a fixation member 600, which can be used in any of the above embodiments, includes through bores 610, 620 with radiused corners 615 to reduce friction between suture 470 and fixation member 600. Referring to FIG. 26, another embodiment of a fixation member 650, which can be used in any of the above embodiments, includes a solid rod 660 with ends 680, 690, and a braided suture 670 attached to ends 680, 690. Suture 670 forms a loop 700 for receiving suture 10 or suture 310. Loop 700 lines up with suture 10, 310 to act as a pulley and reducing friction between the suture and fixation member.

WHAT IS CLAIMED IS:

- 1 1. A surgical method, comprising:
2 positioning a fixation member relative to tissue,
3 moving a flexible member coupled to the fixation member relative to the fixation
4 member to bring two tissue surfaces together, and
5 moving a retaining element coupled to the flexible member relative to the fixation
6 member, the retaining element acting to limit loosening of the flexible member relative to the
7 fixation member.
- 1 2. The surgical method of claim 1 wherein the step of moving the flexible member
2 comprises pulling the flexible member.
- 1 3. The surgical method of claim 1 wherein the step of moving the flexible member also
2 accomplishes the step of moving the retaining element.
- 1 4. The surgical method of claim 3 further comprising providing the retaining element in
2 the form of a slip knot.
- 1 5. The surgical method of claim 1 wherein the step of moving the retaining element
2 includes moving the retaining element relative to the flexible element.
- 1 6. The surgical method of claim 5 further comprising providing the retaining element in
2 the form of a friction element which permits sliding of the retaining element relative to the
3 flexible element in only one direction.
- 1 7. The surgical method of claim 1 further comprising providing the retaining element in
2 the form of an overhand knot.
- 1 8. The surgical method of claim 7 further comprising advancing the overhand knot
2 along the flexible element.

1 19. The surgical method of claim 18 further comprising positioning the loop within a tear
2 in soft tissue.

1 20. A method for repairing a tear in soft tissue, comprising:
2 advancing a fixation member coupled to a flexible member through tissue on either side
3 of the tear and through a loop of the flexible member, and
4 tensioning the flexible member to bring two tissue surfaces on either side of the tear
5 together.

1 21. The method of claim 20 further comprising positioning the loop within the tear.

1 22. The method of claim 20 further comprising pulling an end of the flexible member to
2 bring the two tissue surfaces together.

1 23. The method of claim 20 further comprising providing the fixation member in the
2 form of a barbed member.

1 24. An apparatus for repairing a tear in soft tissue, comprising:
2 at least two fixation members,
3 a flexible member substantially immovably secured to a first of the fixation members and
4 movably coupled to a second of the fixation members, and
5 a retaining element coupled to the flexible member, the retaining element being movable
6 relative to the second fixation member and acting to limit loosening of the flexible member
7 relative to the second fixation member.

1 25. An apparatus for repairing a tear in soft tissue, comprising:
2 at least two fixation members,
3 a flexible member substantially immovably secured to a first of the fixation members and
4 movably coupled to a second of the fixation members, and
5 a retaining element coupled to the flexible member, the retaining element being slidably
6 received by the flexible member and acting to limit loosening of the flexible member relative
7 to the second fixation member.

1 33. The device of claim 30 wherein one of the holding elements comprises a ramp
2 extending into a lumen of the needle.

1 34. The device of claim 30 wherein the needle defines a slot through a wall of the needle,
2 the first and second fixation members extending through the slot.

1 35. The device of claim 30 further comprising a protector tube, the tube defining a bore,
2 wherein the needle is sized to fit into an end of the protector tube.

1 36. The device of claim 30 further comprising a push pin, the pin being sized to fit inside
2 the needle.

2/28

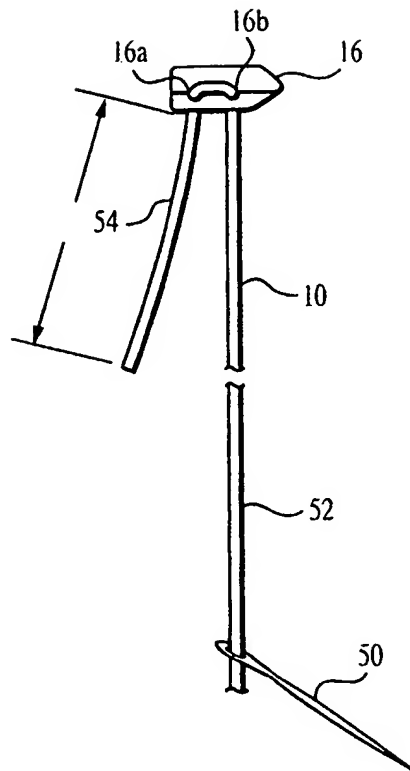


FIG. 2A

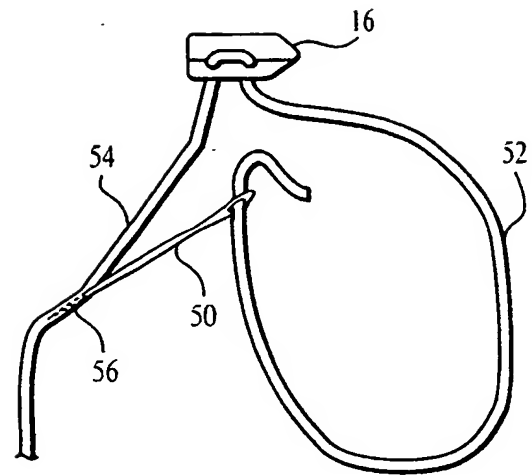


FIG. 2B

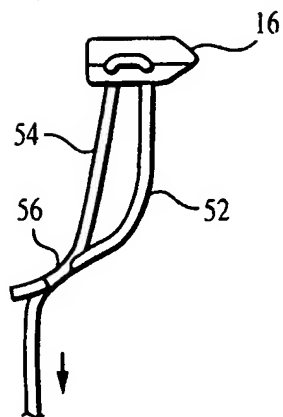


FIG. 2C

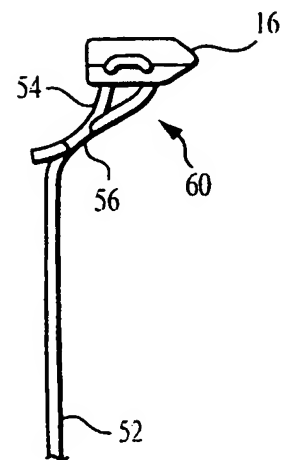


FIG. 2D

4/28

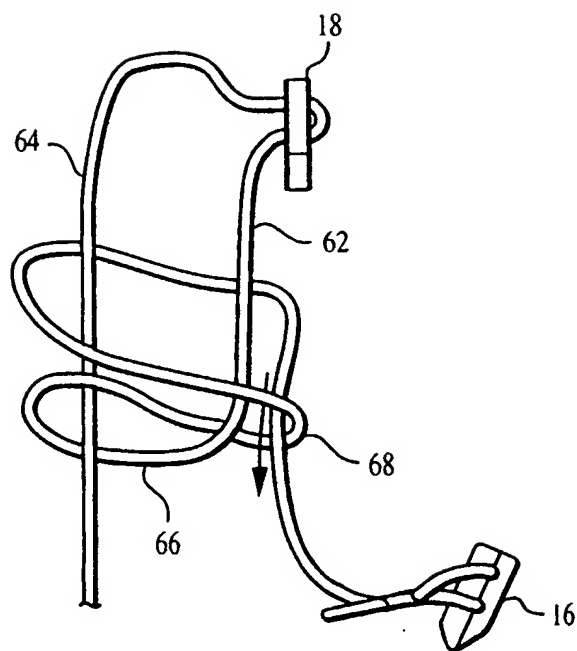


FIG. 2H

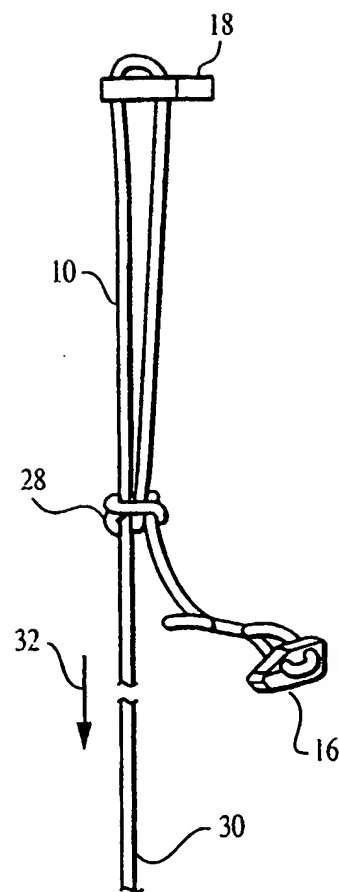


FIG. 2I

6/28

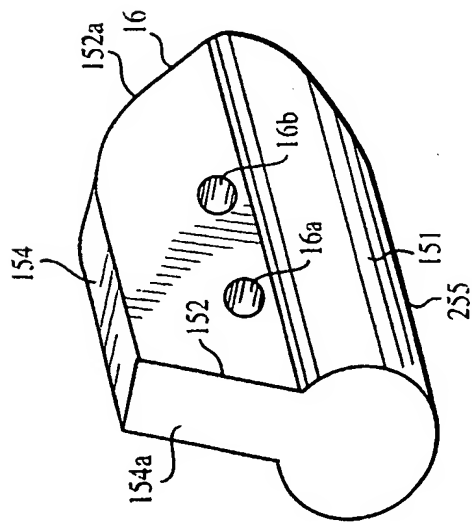


FIG. 4A

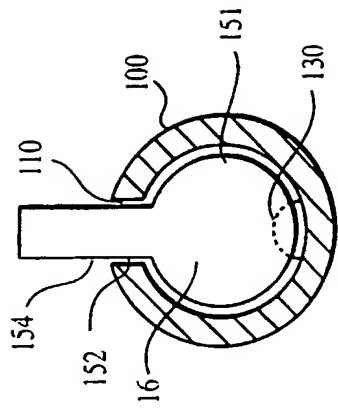


FIG. 4B

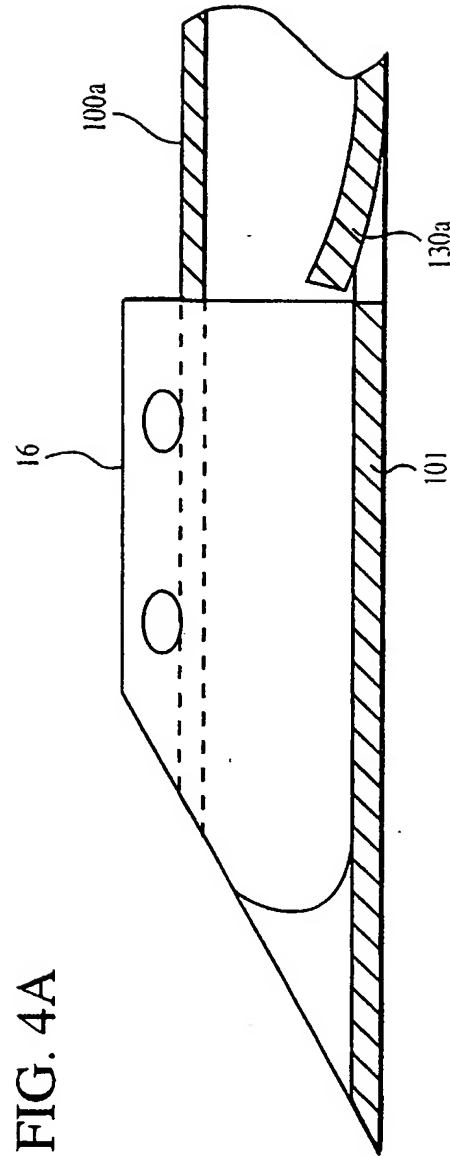


FIG. 4C

8/28

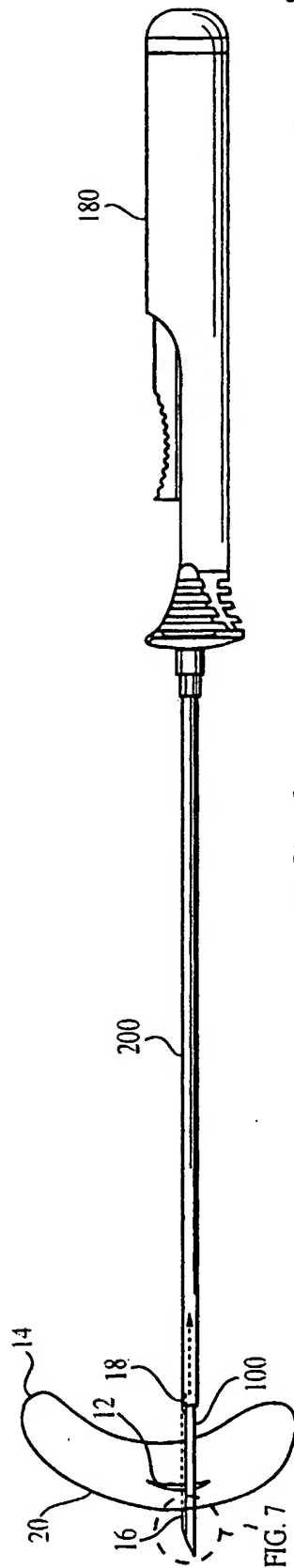


FIG. 6

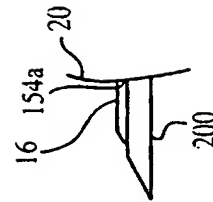
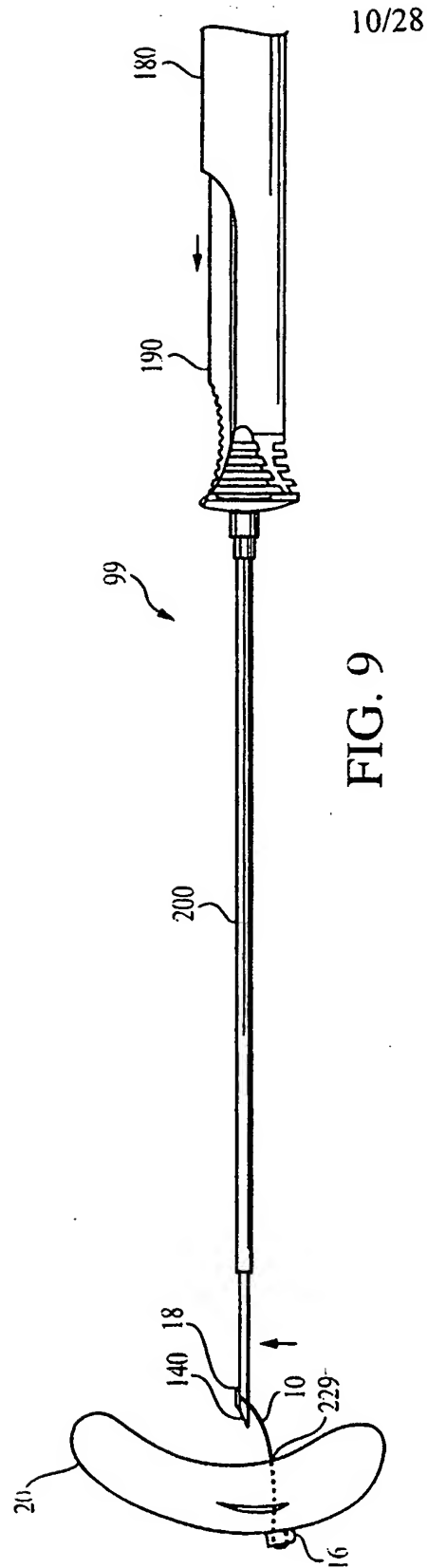
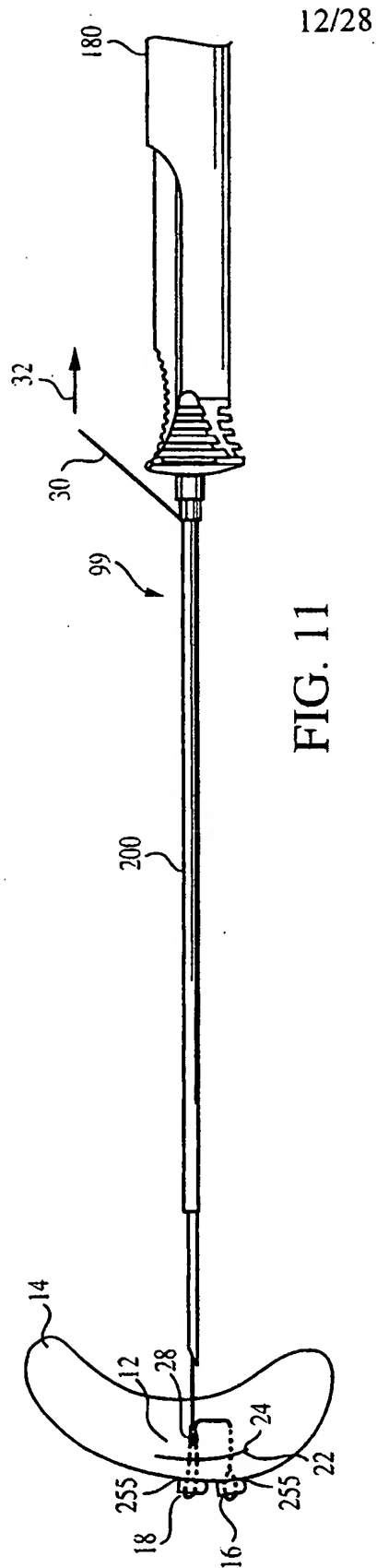


FIG. 7





14/28

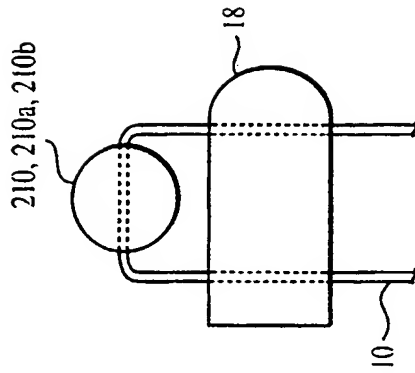


FIG. 12C

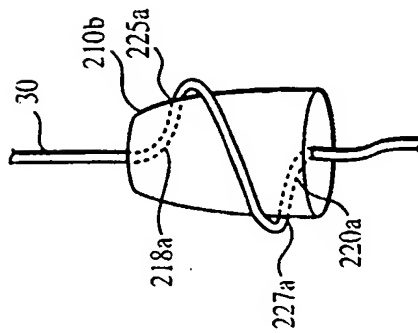


FIG. 12B

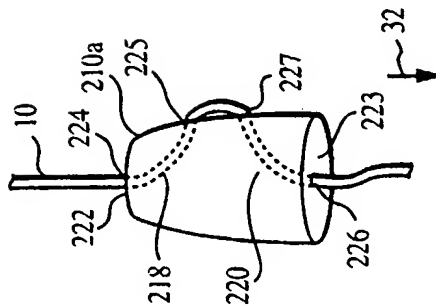


FIG. 12A

18/28

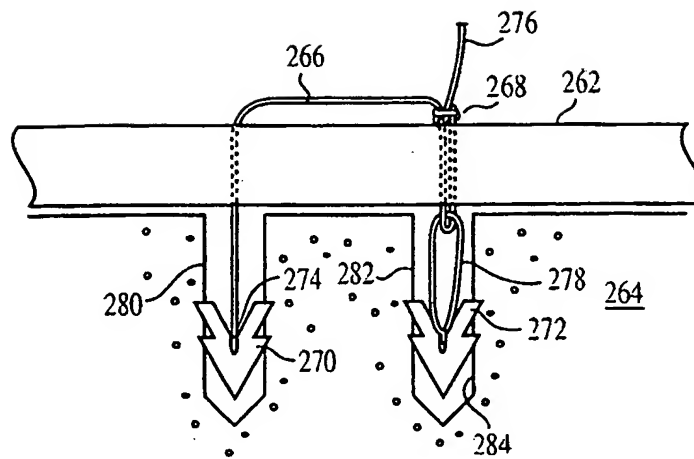


FIG. 15

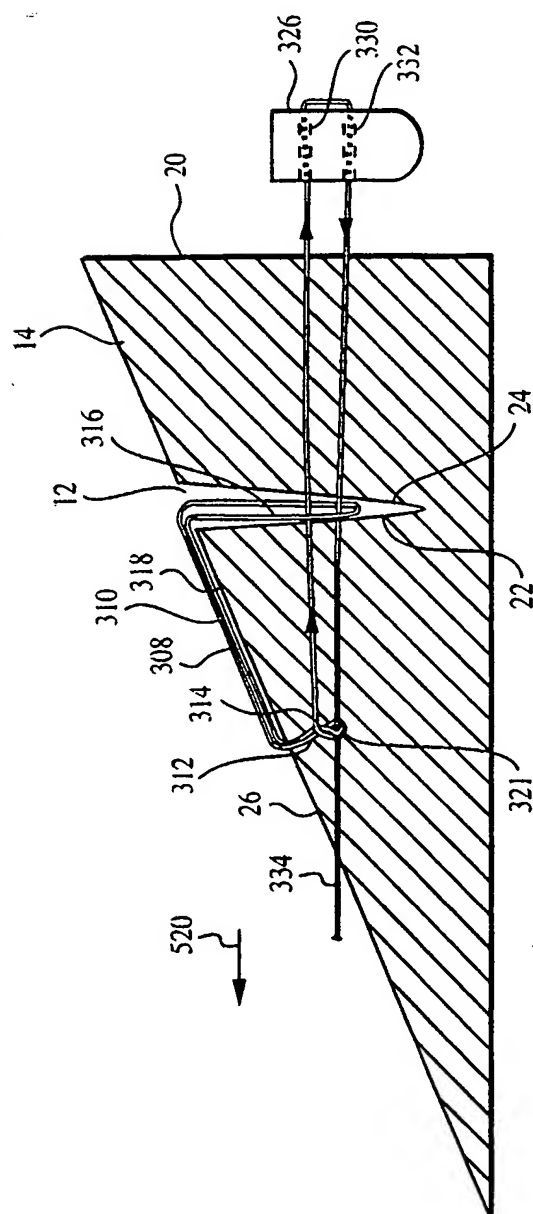


FIG. 17

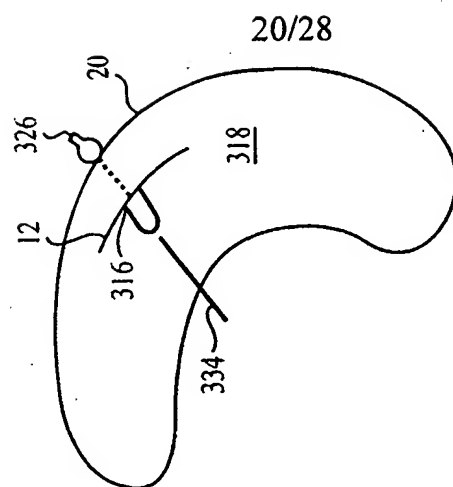


FIG. 18

22/28

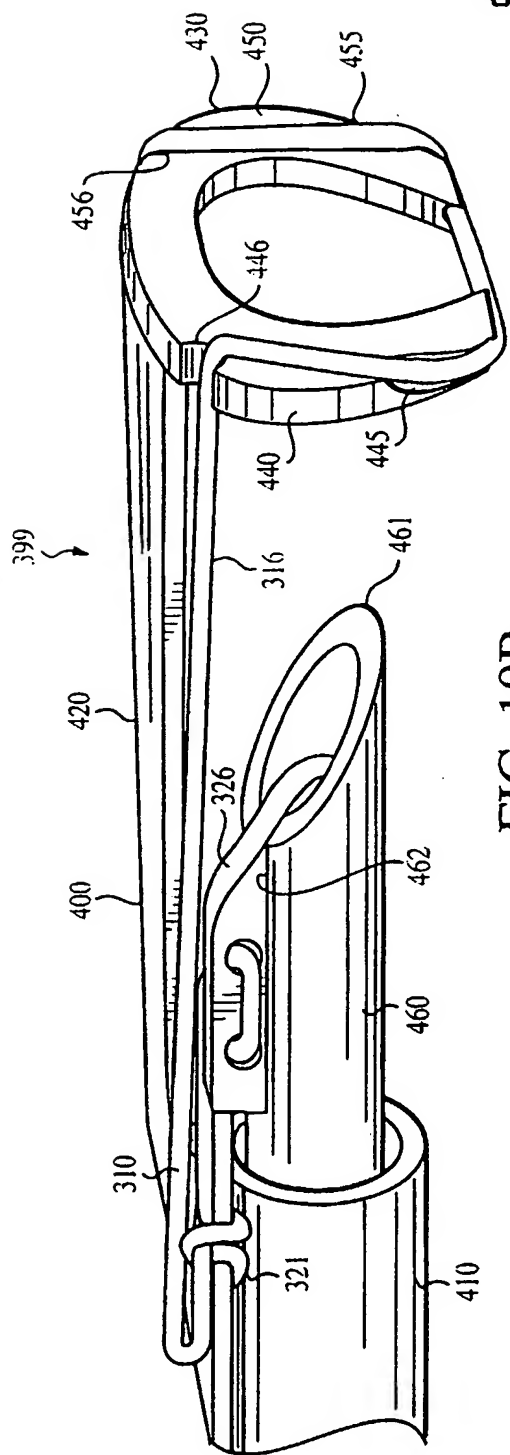


FIG. 19B

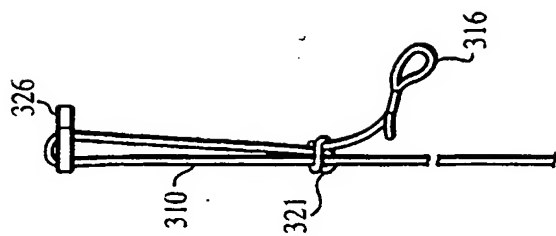


FIG. 19C

24/28

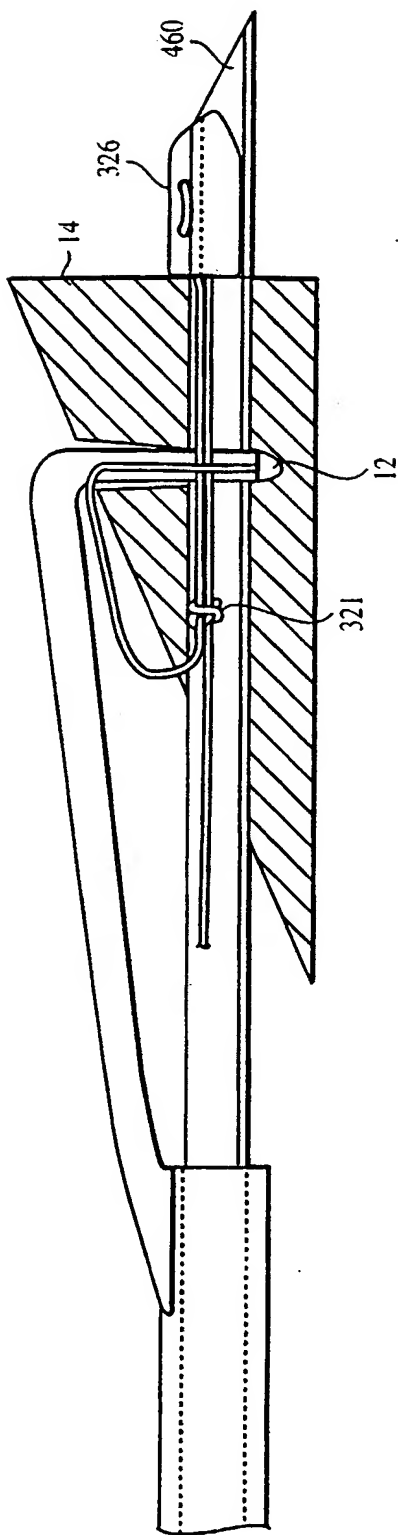


FIG. 21

26/28

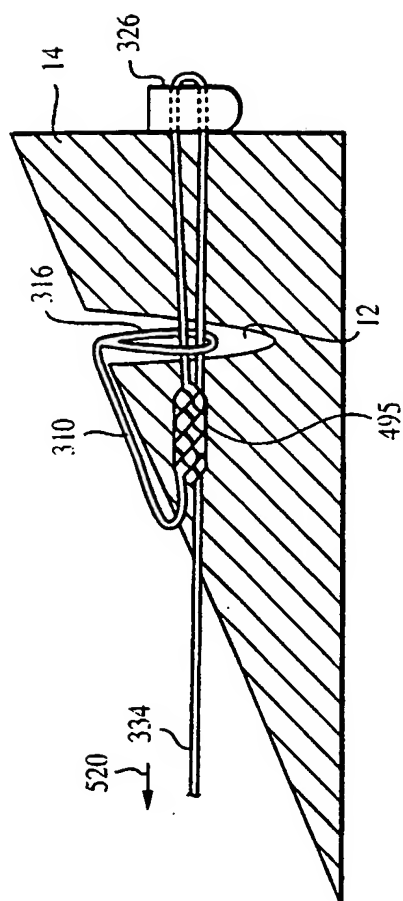


FIG. 23

28/28

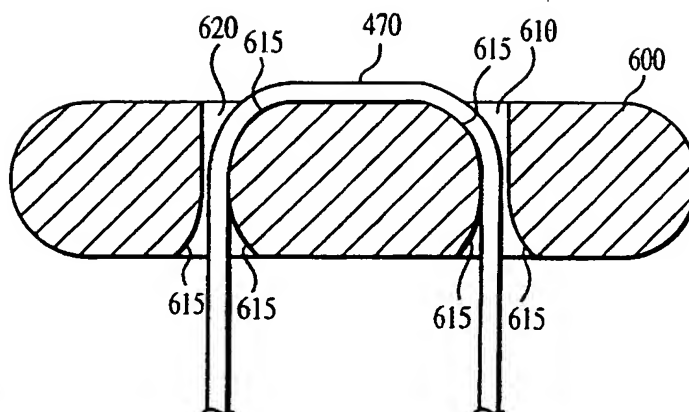


FIG. 25

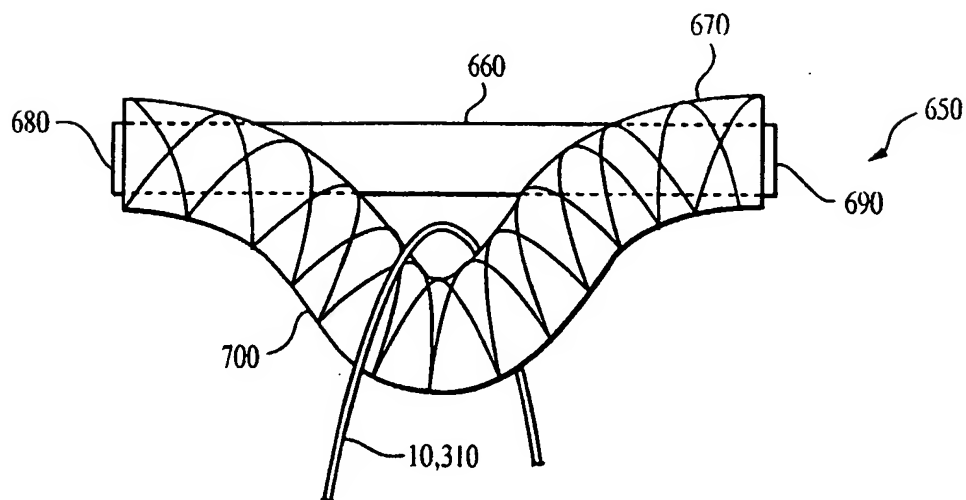


FIG. 26

INTERNATIONAL SEARCH REPORT

In Application No.
PCT/US 01/32625

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3 910 281 A (KLETSCHKA ET AL.) 7 October 1975 (1975-10-07) abstract; figures	26
P, X	WO 01 39671 A (SMITH & NEPHEW, INC.) 7 June 2001 (2001-06-07) the whole document	24-36